

# **REDACTED DOCUMENTS RELATING TO DOCKET 7317**

**EXHIBIT A – No redactions**

**EXHIBIT B – Previously filed redacted in  
DKT 8118**

**EXHIBIT D – No redactions**

**EXHIBIT E – Previously filed redacted in  
DKT 8118**

**EXHIBIT F – Filed redacted**

# **EXHIBIT A**



Deposition of:  
**Robert Ritchie , Ph.D.**

*June 9, 2017*

In the Matter of:  
**In Re: Bard IVC Filters Products  
Liability**

**Veritext Legal Solutions**  
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Robert Ritchie, Ph.D.  
In Re: Bard IVC Filters Products Liability

June 9, 2017

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

In re Bard IVC Filters  
Products Liability Litigation

No. MD-15-02641-PHX-DGC

DEPOSITION OF:  
ROBERT O. RITCHIE, Ph.D.  
June 9, 2017

REPORTER'S TRANSCRIPT OF PROCEEDINGS  
BY Jill Anne Stephenson, CSR 8563

Robert Ritchie, Ph.D.  
In Re: Bard IVC Filters Products Liability

June 9, 2017

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES</p> <p>2</p> <p>3 FOR PLAINTIFF: JOHN DALIMONTE</p> <p>4 DALIMONTE RUEB</p> <p>5 85 DEVONSHIRE STREET STE 1000</p> <p>6 BOSTON, MA 02109</p> <p>7 john@drilawllp.com</p> <p>8</p> <p>9 FOR DEFENSE: TAYLOR DALY</p> <p>10 NELSON MULLINS RILEY SCARBOROUGH</p> <p>11 201-17TH STREET NW STE. 1700</p> <p>12 ATLANTA, GA 30363.</p> <p>13 taylor.daly@nelsonmullins.com</p> <p>14</p> <p>15 ALSO PRESENT TELEPHONICALLY:</p> <p>16 FOR DEFENSE: RAMON LOPEZ</p> <p>17 LOPEZ MCHUGH, LLP</p> <p>18 100 BAYVIEW CIRCLE</p> <p>19 NORTH TOWER STE. 5600</p> <p>20 NEWPORT BEACH, CA 93660</p> <p>21</p> <p>22 FOR DEFENSE: MARK O'CONNOR</p> <p>23 GALLAGHER &amp; KENNEDY</p> <p>24 2575 E. CAMELBACK RD. STE. 1100</p> <p>25 PHOENIX, AZ 85016</p> <p>markoconnor@gknet.com</p> <p>26</p> <p>27 VIDEOGRAPHER: JOE MARGOULIS, EUREKA STREET VIDEO</p> <p>28</p> <p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p> <p>35</p>	<p style="text-align: right;">Page 4</p> <p>1 EXHIBITS</p> <p>2</p> <p>3 PLAINTIFF'S EXHIBITS</p> <p>4 Exhibit 1 Notice of Deposition, 5 pgs.</p> <p>5 Exhibit 2 3.2.17 Assessment of the Structural Integrity of</p> <p>6 Bard IVC Filters: Recovery, G2, G2-Express</p> <p>7 and Eclipse; 121 pgs.</p> <p>8 Exhibit 3 4.1.17 Rebuttal to Defendants' Experts' Opinions</p> <p>9 of Assessment of the Structural Integrity of</p> <p>10 Bard IVC Filters: Recovery, G2, G2-Express</p> <p>11 and Eclipse; 27 pgs.</p> <p>12</p> <p>13 Exhibit 4 4.1.17 Supplementary Report, 3 pgs.</p> <p>14</p> <p>15 Exhibit 5 List of various filters, 2 pgs.</p> <p>16</p> <p>17 Exhibit 6 Excerpt of Ritchie Motion Hearing; 35 pgs.</p> <p>18</p> <p>19 Exhibit 7 McMeeking Assessment of the Designs of Bard Inferior</p> <p>20 Vena Cava Filters; 173 pgs.</p> <p>21 Exhibit 8 4.7.17 McMeeking Supplementary Report; 12 pgs.</p> <p>22 Exhibit 9 5.11.17 McMeeking Rebuttal Report; 20 pgs.</p> <p>23 Exhibit 10 3.17.17 Ritchie Invoice to Lopez; 1 pg.</p> <p>24 Exhibit 11 3.11.16 Ritchie invoice to Lopez; 1 pg.</p> <p>25</p> <p>26</p> <p>27</p> <p>28</p> <p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p> <p>35</p>
<p style="text-align: right;">Page 3</p> <p>1 INDEX OF EXAMINATION</p> <p>2</p> <p>3 ROBERT O. RITCHIE</p> <p>4</p> <p>5 DIRECT EXAMINATION BY MS. DALY, PG. 6</p> <p>6 CROSS-EXAMINATION BY MR. DALIMONTE, PG. 147</p> <p>7 REDIRECT EXAMINATION BY MS. DALY, PG. 160</p> <p>8 RECROSS EXAMINATION BY MR. DALIMONTE, PG. 164</p> <p>9</p> <p>10 QUESTIONS INSTRUCTED NOT TO ANSWER</p> <p>11 NONE</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 5</p> <p>1 VIDEOGRAPHER: Here begins Video No. 1 in the</p> <p>2 deposition of Robert O. Ritchie, Ph.D in re: Bard IVC</p> <p>3 Filters Products Liability Litigation venued in the</p> <p>4 United States District Court for the District of</p> <p>5 Arizona. The case number is MD-15-02641-PHX-DOC.</p> <p>6 Today's date is June 9, 2017, and the time on the video</p> <p>7 monitor is 10:07 a.m.</p> <p>8 The video operator today is Joseph Morgous</p> <p>9 representing Veritext Legal Solutions. This video</p> <p>10 deposition is taking place at 2140 Shattuck Avenue Suite</p> <p>11 407, Berkeley, California and was noticed by Nelson</p> <p>12 Mullins, Riley &amp; Scarborough, LLP.</p> <p>13 Counsel, please voice-identify yourselves and</p> <p>14 state whom you represent.</p> <p>15 MR. DALIMONTE: Good morning, my name is John</p> <p>16 Dalimonte from the law firm of Dalimonte Rueb in Boston,</p> <p>17 Massachusetts, on behalf of the plaintiffs.</p> <p>18 MS. DALY: And I'm Taylor Daly, for the BARD</p> <p>19 defendants.</p> <p>20 VIDEOGRAPHER: The court reporter today is Jill</p> <p>21 Stephenson representing Veritext Legal Solutions. Would</p> <p>22 the reporter please administer the oath?</p> <p>23 BE IT REMEMBERED that, pursuant to Notice of</p> <p>24 Deposition, and on June 9, 2017 commencing at the hour</p> <p>25 of 10:07 a.m. at Clark Reporting &amp; Video Conferencing,</p>

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Robert Ritchie, Ph.D.  
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<p style="text-align: right;">Page 6</p> <p>1 Berkeley, California, before me, Jill Stephenson, CSR</p> <p>2 8563, State of California, there personally appeared</p> <p>3 John O. Ritchie,</p> <p>4 who was provided as a witness under the provisions of</p> <p>5 the Superior Court of California.</p> <p>6 DIRECT EXAMINATION BY</p> <p>7 MS. DALY: Q. Good morning, Dr. Ritchie.</p> <p>8 A. Good morning.</p> <p>9 Q. Exhibit 1 is before you, and that's the Notice</p> <p>10 of Deposition for today.</p> <p>11 A. No, it's not.</p> <p>12 Q. What did you bring with you?</p> <p>13 A. No, it's not.</p> <p>14 Q. What? It's not? Oh. It's the McMeeking</p> <p>15 notice.</p> <p>16 Let's make this one No. 1 instead. Can I have</p> <p>17 one more?</p> <p>18 (Whereupon, Exhibit 1 was</p> <p>19 marked for identification.)</p> <p>20 Q. Starting again, Exhibit 1 before you is the</p> <p>21 Notice of Deposition for the deposition today, correct?</p> <p>22 A. It is, indeed.</p> <p>23 Q. What have you brought with you today?</p> <p>24 A. Not very much, actually. I brought bills, and</p> <p>25 -- and in the words of Oscar Wilde, I brought my</p>	<p style="text-align: right;">Page 8</p> <p>1 MS. DALY: -- I'm going to take my seven hours,</p> <p>2 but we'll move along rapidly, as Dr. Ritchie and I are</p> <p>3 usually able to do.</p> <p>4 MR. DALIMONTE: Understood.</p> <p>5 Q. (By Ms. Daly) I am going to give you copies of</p> <p>6 your three reports that I'm going to be talking to you</p> <p>7 about so you have them in front of you. And this -- I</p> <p>8 made a copy already.</p> <p>9 A. I'm going to take my jacket off.</p> <p>10 Q. This is going to be 2.</p> <p>11 (Whereupon, Exhibit 2 was</p> <p>12 marked for identification.)</p> <p>13 MR. DALIMONTE: Thank you. That was 2?</p> <p>14 MS. DALY: Yes.</p> <p>15 MR. DALIMONTE: I see you marked it at the top,</p> <p>16 right.</p> <p>17 Q. (By Ms. Daly) And Exhibit 2, if you would,</p> <p>18 just tell us what that is.</p> <p>19 A. It's a report written by me entitled,</p> <p>20 "Assessment of the Structure Integrity of Bard IVC</p> <p>21 Filters: Recovery, G2, G2-Express and Eclipse."</p> <p>22 Q. And that's on March 2, 2017.</p> <p>23 A. March 2, 2017.</p> <p>24 (Whereupon, Exhibit 3 was</p> <p>25 marked for identification.)</p>
<p style="text-align: right;">Page 7</p> <p>1 intellect.</p> <p>2 Q. Okay. Is there anything new that you rely on</p> <p>3 in your MDL litigation work that was not previously</p> <p>4 listed in the three MDL reports that you have provided</p> <p>5 recently?</p> <p>6 A. I'm not quite certain, but I -- I mean, there</p> <p>7 are things, like I've seen some recent depositions and</p> <p>8 some recent reports, the Fashing report, for example,</p> <p>9 and so I, of course, have looked at those, so they</p> <p>10 certainly could have influenced me in some respects, but</p> <p>11 basically it's much the same.</p> <p>12 Q. All right, but nothing -- nothing new that I</p> <p>13 wouldn't either know about because it's Dr. Fashing's</p> <p>14 report, or it's already cited as a reference to your</p> <p>15 reports?</p> <p>16 A. I would think everything that's in my report,</p> <p>17 you know about it. It either has a Bates stamp or it's</p> <p>18 been declared. I have not taken any other input from</p> <p>19 anywhere else.</p> <p>20 Q. All right. We got started a little bit late.</p> <p>21 The notice was for 9:00. I know that Mr. Dalimonte</p> <p>22 needed a little time with you this morning, so we got</p> <p>23 started a little bit after 10:00. And I just want to</p> <p>24 make you all understand, if I need my seven hours --</p> <p>25 MR. DALIMONTE: Oh, yeah.</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. All right. And then let me show you what's</p> <p>2 been marked as No. 3, and ask you to tell us what that</p> <p>3 one is.</p> <p>4 A. That's the Rebuttal to the Defendant's Expert</p> <p>5 Opinions, and same title, dated April 1st, 2017.</p> <p>6 (Whereupon, Exhibit 4 was</p> <p>7 marked for identification.)</p> <p>8 Q. All right. And then we have another report</p> <p>9 filed called the MDL, which will be No. 4. Will you</p> <p>10 tell us what that one is?</p> <p>11 A. That's an Assessment of the Structural</p> <p>12 Integrity of Bard IVC Filters: Meridian and Denali</p> <p>13 Filters, dated April 1st, Supplementary Report.</p> <p>14 You want me to repeat that?</p> <p>15 THE REPORTER: No, I got it.</p> <p>16 Q. (By Ms. Daly) Very good. I'm going to be,</p> <p>17 from time to time, referring to one of these three</p> <p>18 reports and a page, and I'll take you there as I ask you</p> <p>19 questions.</p> <p>20 A. Thanks.</p> <p>21 Q. All right. Now, your opinions -- and let's go</p> <p>22 to -- to Exhibit 2, which is your larger report. I want</p> <p>23 to go through some issues about opinions we've talked</p> <p>24 about before.</p> <p>25 A. Okay.</p>

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<p style="text-align: right;">Page 10</p> <p>1 Q. And I want to start with your Opinion I in this</p> <p>2 -- in this report, Exhibit 2, which is the opinion on</p> <p>3 lack of appropriate chamfer causing increased local</p> <p>4 stresses. All right?</p> <p>5 A. Yes.</p> <p>6 Q. All right. First of all, does that opinion</p> <p>7 relate to stresses that will cause fracture, or stresses</p> <p>8 that will cause something else, like tilt or</p> <p>9 perforation?</p> <p>10 A. The chamfer issue is a local elevation of</p> <p>11 stresses, and I would think that it would mainly pertain</p> <p>12 to fracture issues. However, if -- if there was a</p> <p>13 fracture of, for example, a leg or an arm, at that point</p> <p>14 it would obviously affect the other function of the</p> <p>15 device, but -- so you can't rule out, but primarily it's</p> <p>16 a fracture issue.</p> <p>17 Q. The way that you've looked at it, from your</p> <p>18 role in this case, is the chamfer, as it relates to</p> <p>19 fractures, principally, true?</p> <p>20 A. Yeah, but I mean, as I said, you know, there is</p> <p>21 a -- you can't box these things; there is a synergism</p> <p>22 between the various different modes of operation.</p> <p>23 Q. And we'll get to that.</p> <p>24 A. But, yes, the fractures of these parts are due</p> <p>25 to fatigue, and fatigue is motivated by stress, or in</p>	<p style="text-align: right;">Page 12</p> <p>1 examples, quite a few examples, when you look at the</p> <p>2 region on the wires where they're close to the edge of</p> <p>3 the chamfer where you can see what appears to be pretty</p> <p>4 fretting markings, which is associated with contact of</p> <p>5 the wire to the edge of the sheaths.</p> <p>6 Q. All right, well let's -- let's look at the</p> <p>7 chart that you have done in the past of the -- of the</p> <p>8 filters you've reviewed, if we could.</p> <p>9 MR. DALIMONTE: What particular case was this</p> <p>10 chart prepared? I could pull it up.</p> <p>11 MS. DALY: I have no idea. It's been used so</p> <p>12 many times.</p> <p>13 THE DEPONENT: It's just basically a list of</p> <p>14 the various filters I looked at.</p> <p>15 MS. DALY: Let me mark this as 5.</p> <p>16 (Whereupon, Exhibit 5 was</p> <p>17 marked for identification.)</p> <p>18 Q. And if you look at the date on it, I don't know</p> <p>19 that it even contains all the ones you've seen. That's</p> <p>20 the last chart I have for you, I'm sorry. There's one</p> <p>21 on the back.</p> <p>22 MR. DALIMONTE: Can I take a look at that</p> <p>23 document? There you go.</p> <p>24 THE DEPONENT: There is some -- there may be a</p> <p>25 few more. The statistics don't change very much.</p>
<p style="text-align: right;">Page 11</p> <p>1 this case more strain, and there are more sources of</p> <p>2 that stress and strain, and this is one of them,</p> <p>3 potentially one of them.</p> <p>4 Q. Now, in talking about the chamfer, there is, in</p> <p>5 your opinion, the ability of this chamfer or edge to</p> <p>6 actually physically contact a wire leading to fatigue of</p> <p>7 the wire and fracture, true?</p> <p>8 A. Yeah.</p> <p>9 Q. And have you seen that in any of the ones</p> <p>10 you've examined?</p> <p>11 A. Well, you -- I mean, the wires are coming out</p> <p>12 of that, of that rim, and so you're seeing -- seeing a</p> <p>13 snapshot of it after the fact; you're not seeing it in</p> <p>14 real time, right? You'd have to have a CT scan. But it</p> <p>15 will be beyond credibility to think there wasn't contact</p> <p>16 between the wires and the edge of the rim.</p> <p>17 Q. Well, wait, my question was have you seen -- in</p> <p>18 any of the ex-planted filters that you've examined, have</p> <p>19 you seen evidence on any given filter that a wire</p> <p>20 actually came in contact with the edge or chamfer,</p> <p>21 leading to fracture?</p> <p>22 A. Well, again, if it fractured, you wouldn't see</p> <p>23 it anymore, right? But there are -- there are examples</p> <p>24 of where struts have broken off exactly at the point of</p> <p>25 the chamfer, so that led to a fracture. And there are</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. (By Ms. Daly) All right, so let's -- while we</p> <p>2 have the chart in front of us, let's first look at the</p> <p>3 chart, because I have a couple of questions about the</p> <p>4 chart and then I'll go back to my question. Do you see</p> <p>5 on this chart that there is missing any filter that you</p> <p>6 have in fact reviewed before -- examined physically?</p> <p>7 MR. DALIMONTE: Objection.</p> <p>8 THE DEPONENT: I don't know. I mean, this is</p> <p>9 -- the answer to that question is have I examined</p> <p>10 filters since February 2014.</p> <p>11 Q. (By Ms. Daly) Well, it's more than that. My</p> <p>12 question is just --</p> <p>13 A. Have I put -- have I not put any on the chart?</p> <p>14 Q. Yeah. Is there anything missing from this</p> <p>15 chart that you have seen?</p> <p>16 A. As of 2014, these are the Bard filters that I</p> <p>17 have seen.</p> <p>18 Q. All right, what Bard filters have you seen</p> <p>19 since 2014?</p> <p>20 A. Well, I'm not quite certain, but I can -- I can</p> <p>21 check. I haven't seen very many. I've probably seen</p> <p>22 one or two. And the -- and the -- you know, the</p> <p>23 statistics don't change very much.</p> <p>24 Q. Well, on a -- on a break -- and I'd like to</p> <p>25 have it be a break because I want to keep it moving --</p>

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<p style="text-align: right;">Page 14</p> <p>1 I'd like to know if there are any additional filters</p> <p>2 that you've seen that aren't on this chart, because this</p> <p>3 is the only place I have them all together, other than</p> <p>4 digging through your report. So if we can do that.</p> <p>5 MR. DALIMONTE: If I may add, we know two off</p> <p>6 the top of my head would be Jones and Keene, right?</p> <p>7 MS. DALY: Jones is on here.</p> <p>8 MR. DALIMONTE: Oh, is it?</p> <p>9 THE DEPONENT: There's a different Jones, isn't</p> <p>10 it?</p> <p>11 MR. DALIMONTE: Yeah, so -- well --</p> <p>12 MS. DALY: Well, you can help him, but I would</p> <p>13 like to have --</p> <p>14 THE DEPONENT: There isn't very many, though.</p> <p>15 There really isn't very many, but there may be one or</p> <p>16 two.</p> <p>17 MS. DALY: Okay. We'll figure that out.</p> <p>18 Q. The other thing is, with respect to the five</p> <p>19 Bellweather cases -- you know what I'm talking about?</p> <p>20 A. Yes, I do.</p> <p>21 Q. You are going to get an opportunity to see the</p> <p>22 Booker filter; you understand that?</p> <p>23 A. Yes, that's good to know.</p> <p>24 Q. We're working on figuring out how to get that</p> <p>25 processed.</p>	<p style="text-align: right;">Page 16</p> <p>1 don't tend to make mistakes like that, but it could have</p> <p>2 gotten mis-listed, but I don't think so.</p> <p>3 MR. DALIMONTE: Well, just a backup, too, when</p> <p>4 you refer to G2, are you also including G2-Express?</p> <p>5 MS. DALY: No, because you see, below, he's got</p> <p>6 a G2 --</p> <p>7 MR. DALIMONTE: I saw that; I just wanted a</p> <p>8 clarification.</p> <p>9 Q. (By Ms. Daly) Below, you have a G2-Express,</p> <p>10 and we've called them -- do you call a G2-X and a</p> <p>11 G2-Express, that's the same thing?</p> <p>12 A. I mean, my understanding is they're identical.</p> <p>13 The name may have changed, likely, but I use the terms</p> <p>14 interchangeably.</p> <p>15 Q. That's fine. You have listed on this chart</p> <p>16 having seen the Seale G2-X.</p> <p>17 A. Yes.</p> <p>18 Q. You see that?</p> <p>19 A. Yes.</p> <p>20 Q. What I saw in your report was you also</p> <p>21 commented on seeing a Milton G2-Express, so that's one I</p> <p>22 know is not on this list, and I've -- I've written it on</p> <p>23 my own.</p> <p>24 A. Okay. I can dig that out.</p> <p>25 Q. All right.</p>
<p style="text-align: right;">Page 15</p> <p>1 A. And all the remnants, all the remnants as well.</p> <p>2 Q. I don't know what's with it, actually. But I'm</p> <p>3 not aware of filter fragments or filters in any of the</p> <p>4 other four cases.</p> <p>5 A. That's my understanding, too. By the way,</p> <p>6 those reports are due today, so presumably I can look at</p> <p>7 the filter and amend.</p> <p>8 Q. Yes. They should have told you that.</p> <p>9 Plaintiffs should have told you that we agreed to that.</p> <p>10 A. Yes.</p> <p>11 Q. Now, if you look down your list here, look at</p> <p>12 where it comes to Baluska -- Belusko? (sic)</p> <p>13 A. Yes.</p> <p>14 Q. So you have three filters in a row there,</p> <p>15 Belusko, Davis and Cason; it says that you are unable to</p> <p>16 examine those.</p> <p>17 A. Yes.</p> <p>18 Q. Okay. So for the G2 filters -- oh, and one</p> <p>19 other question. Beckfield, would you look at the</p> <p>20 Beckfield one?</p> <p>21 A. Yes.</p> <p>22 Q. Do you know -- I have that as a Recovery</p> <p>23 filter, not a G2. Do you know, one way or the other?</p> <p>24 A. Offhand, no. I mean, I -- I find that hard to</p> <p>25 believe, but, okay. But I -- that's -- it could be -- I</p>	<p style="text-align: right;">Page 17</p> <p>1 MR. DALIMONTE: Well, I'm going to object to --</p> <p>2 you know, we'll do what we can, but we're not going to</p> <p>3 say it's a complete list until he gets to his office.</p> <p>4 He can get back to you -- agree to get back to you</p> <p>5 Monday.</p> <p>6 MS. DALY: Well, I'm going to redepose him</p> <p>7 anyway on the case specifics, so we could do that at</p> <p>8 that time.</p> <p>9 MR. DALIMONTE: Yeah, all right. I don't see</p> <p>10 the point in wasting time.</p> <p>11 THE DEPONENT: What I can do, if I'm given a</p> <p>12 bit of time, which I will, I'll revise this, check the</p> <p>13 Beckfield with this. And as I said, there may be two or</p> <p>14 three more I can add.</p> <p>15 MS. DALY: That would -- that would be great.</p> <p>16 Thank you.</p> <p>17 Q. All right. So going -- using your chart that</p> <p>18 you have there and going back to my question, of the</p> <p>19 ones that you have examined, tell me which ones you</p> <p>20 identified as having a fracture that was caused by,</p> <p>21 first, actual contact of wire to the chamfer edge.</p> <p>22 A. Well, you're asking the exact question; it's</p> <p>23 difficult to give you an exact answer to that, because</p> <p>24 it's like saying, "Why do people die?"</p> <p>25 Q. No, I don't think it's at all like that.</p>

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In Re: Bard IVC Filters Products Liability

June 9, 2017

<p style="text-align: right;">Page 18</p> <p>1 A. It is, because you can't -- the point about</p> <p>2 fatigue is it's driven by stress or strain, and there</p> <p>3 are multiple sources of stress and strain. So --</p> <p>4 Q. Let me -- let me be really clear in my</p> <p>5 question, because we'll move to the second part. My</p> <p>6 question is, in which filters did you see evidence, on</p> <p>7 the remaining part of the strut or on the edge of the</p> <p>8 chamfer, that a -- that a strut of the filter had --</p> <p>9 that fracture had been in direct contact with the</p> <p>10 chamfer? That's my first question.</p> <p>11 A. Well, to answer that briefly and sort of</p> <p>12 approximately, I would think that there is -- there's</p> <p>13 always contact between the edge of the wires and the</p> <p>14 filter, so the -- so the rim of the sheath and the --</p> <p>15 and the wires. So the question is, then, if a fracture</p> <p>16 occurred exactly at the rim where specifically the</p> <p>17 stresses should be higher so the strain should be</p> <p>18 highest anyway, then you would make the pretty sound</p> <p>19 assumption that was associated with contact there, and</p> <p>20 the stress concentration caused by that. And of the</p> <p>21 filters I looked at in the G2s, there are three you can</p> <p>22 identify --</p> <p>23 Q. That's my question.</p> <p>24 A. -- fractures and that's the Cadbury, (sic) the</p> <p>25 Beckfield and the Gaskins.</p>	<p style="text-align: right;">Page 20</p> <p>1 of fractures of the arms appear in this region where the</p> <p>2 arms come out of the sheath. And there are basically</p> <p>3 two nominal locations. The commonest one is just a</p> <p>4 little bit above the sheath, about a hundred microns,</p> <p>5 which is very small, two human hairs above the -- above</p> <p>6 the sheath. And there's a bend there, and there's also</p> <p>7 evidence of gouge marks which are caused by the shape</p> <p>8 setting.</p> <p>9 And in that whole region, that little region</p> <p>10 above the sheath is where the stresses get very high</p> <p>11 because they're bending. So most of them form there,</p> <p>12 but a few of them form exactly at the rim, and they're</p> <p>13 just flush with the rim. So it's to the -- to a person</p> <p>14 on the street, it's the same location, but most of them</p> <p>15 are a little bit above that, about 100 microns above.</p> <p>16 So you can look at those. Of that sequence of</p> <p>17 fractures of the arms, they virtually all occur in that</p> <p>18 region. But of that, of those -- and there's 17 that I</p> <p>19 look at there -- 22%, like four of them, actually fail</p> <p>20 at the rim. So the perception there, a pretty strong</p> <p>21 one, would be that the -- that the -- the chamfer was</p> <p>22 pretty important.</p> <p>23 Q. In those G2s.</p> <p>24 A. Yeah.</p> <p>25 Q. So then in your G2-Express --</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. Ciaburri --</p> <p>2 A. "Ciaburri," okay.</p> <p>3 Q. Beckfield and Gaskin.</p> <p>4 A. So there's not a lot of them, of the -- of the</p> <p>5 -- the arms that broke, 20% probably, four of them broke</p> <p>6 that way, but they do break exactly at the point of the</p> <p>7 rim.</p> <p>8 Q. Okay. So on your categories at the top, which</p> <p>9 of those categories tells me that the Ciaburri filter</p> <p>10 fractured because of the chamfer?</p> <p>11 A. Okay, let me just go through this, because</p> <p>12 we've had this problem before.</p> <p>13 Q. Yeah.</p> <p>14 A. So the first column talks about how many of</p> <p>15 these, these struts failed by fatigue --</p> <p>16 Q. Right.</p> <p>17 A. And virtually every one failed by fatigue.</p> <p>18 Q. Right.</p> <p>19 A. And then subsequently by the ductile fracture.</p> <p>20 The next two columns determined which way the</p> <p>21 cracks are growing, whether they're growing from the</p> <p>22 outside of the filter in or the inside of the filter</p> <p>23 out. But they're not mutually exclusive, these columns.</p> <p>24 Q. Right.</p> <p>25 A. The third -- so that the main, the main sources</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Yes.</p> <p>2 Q. The only one you have on here is Seale.</p> <p>3 A. Yes.</p> <p>4 Q. You do not show a fracture at the rim on that</p> <p>5 filter.</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Do you recall that Milton also did not</p> <p>8 have a fracture there?</p> <p>9 MR. DALIMONTE: Objection.</p> <p>10 THE DEPONENT: I don't --</p> <p>11 Q. (By Ms. Daly) We'll find Milton when we go</p> <p>12 through your report.</p> <p>13 Okay, so let's look at the Recovery filters on</p> <p>14 the next page.</p> <p>15 A. Yeah.</p> <p>16 Q. And your -- of the ones that you looked at that</p> <p>17 were Recovery, how many of those are fractures that you</p> <p>18 associate with the chamfer? And I'm looking at the</p> <p>19 fourth column. Is it all of those?</p> <p>20 A. No, I mean -- yes, it's -- I mean, again, all</p> <p>21 the arm fractures occur in this region within 100</p> <p>22 microns, the top of the sheath, and the -- of those, 25%</p> <p>23 now as opposed to the 22% in the ones I looked at,</p> <p>24 fractured exactly at the point of the rim. So the</p> <p>25 chamfer, clearly, would not be unimportant there.</p>

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<p style="text-align: right;">Page 22</p> <p>1 Q. So if the -- if the chamfer is a contributing 2 factor to the fracture, one would see it either -- one 3 would see it very close to the rim. Is that right? 4 A. Well, the stress concentration effects are 5 pretty localized, so now -- I mean, I don't know -- 6 specifically it's this. If the chamfer has a radius say 7 of 50 microns, you'd expect the effect of the stress 8 concentration of that chamfer to be felt within about 9 one to two radii away from that. So 50 to 100 microns. 10 So you can't be precise. 11 Q. So if the -- if the arm fractures below the 12 elbow, for example, would you say that probably was not 13 associated -- 14 A. No, because that's only 100 microns above, 15 right; so you're still potentially in the -- in the 16 regime where that edge would be affected. But, quite 17 frankly, it's getting to the point of where it's -- it's 18 becoming less important. It's on the edge of the field 19 there. 20 So -- so, I -- my take on this, again, you can 21 not be precise because there's so many different forces 22 playing a role in these things. But where they break a 23 little bit further up near the first bend, you're in the 24 same nominal location where the stresses and strains are 25 high. But there's also some markings there. Those</p>	<p style="text-align: right;">Page 24</p> <p>1 them, whether they chose them randomly or not, but as 2 far as I know. 3 Q. It wasn't random. Okay. Who performed the 4 actual SEM examination that was done? 5 A. Well, I -- I mean, I'm old now, so I sit there, 6 but I have a technician who does that for me. 7 Q. Do you direct what the technician is doing? 8 A. Absolutely. 9 Q. So with respect to the chamfer for a minute, do 10 you -- do you know exactly which of the Recovery filters 11 that show the cracks at the rim -- are there any of 12 those that have evidence of -- of precise rubbing of the 13 fractured rim against the chamfer, or do you just see it 14 in the area? 15 A. They're -- I mean, specifically, I don't know 16 exactly, but in many cases when you look at the region 17 where the wires are emerged from the rim, right, I mean, 18 -- it's -- it's not a very good engineering feature 19 because there can be contact and they're all bunched 20 together. So inevitably you will see contact between 21 the individual wires and you will see contact between 22 the edge of the rim, and sometimes you see little, you 23 know, markings there which are clearly caused by that 24 contact. 25 This is quite a phenomenon plagued aerospace,</p>
<p style="text-align: right;">Page 23</p> <p>1 shaped markings don't help things either, so you can't 2 be precise. But, definitely, when they break at the 3 rim, to say that the chamfer is unimportant would be -- 4 would be very difficult to say. 5 Q. Have you -- have you seen leg fractures that 6 you think were associated with chamfer? 7 A. No. 8 Q. Now, this is obvious, but I want to put it on 9 the record. The filters that you have examined in your 10 work in this litigation which are not exemplars are all 11 retrieved filters that were sent to you because a 12 patient had had a complication, true? 13 A. Well, there's a few that don't have any -- I 14 mean, they may have had a medical complication, but 15 there's no fractures. It was one or two that looked 16 perfectly -- looked fine, right -- 17 Q. Right. 18 A. -- in terms of fractures. But, not -- yes, the 19 answer to that question is. 20 Q. My point being, you weren't sent some randomly 21 retrieved filters; these were filters that were sent to 22 you to look at, usually for fracture, correct? 23 A. Correct. 24 Q. All right. 25 A. Well, I mean, I can't speak to how they chose</p>	<p style="text-align: right;">Page 25</p> <p>1 and when you get two bits of metal rubbing together, you 2 get fretting and it can lead to -- it can lead -- it can 3 initiate fatigue cracks. 4 Q. Do you have any examples of the filters that 5 you've seen, that show contact with the chamfer, that 6 are not fractured? 7 A. Yes. 8 Q. Can you think of one to show me? 9 A. Yes. Give me a second. I have a picture, I'm 10 sure. I've looked at too many of these things. This 11 may take a second, okay? 12 Q. Sure. 13 A. Well, there's one example there; maybe it's not 14 the best, but you can see the edge of the rim there? 15 It's not so clear. 16 Q. Yeah, I've got mine. You can hold on to -- 17 you're on Page 12? 18 A. I'm on Page 12, and it's Figure 14, yes. 19 Q. That's the Mata? 20 A. Yeah, and that's -- you can see a little bit of 21 a -- an undercut and gouge there. You can see the 22 contact there on the lower right one where it's actually 23 touching the rim. And that -- it didn't break there, of 24 course, necessarily, but, nevertheless, you can see that 25 contact.</p>

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<p style="text-align: right;">Page 26</p> <p>1 And -- and there are few other examples, on</p> <p>2 Page 17, for example, and that's on the -- you can see</p> <p>3 that one -- that one -- it's not actually at the rim,</p> <p>4 but it's close to the rim there.</p> <p>5 Q. Which figure was that one? Figure 17?</p> <p>6 A. Yeah.</p> <p>7 Q. And that one was the Ciaburri -- no, Carnehl.</p> <p>8 And, again, it's a G2.</p> <p>9 A. Yeah.</p> <p>10 Q. Okay.</p> <p>11 A. But you can see -- I mean, you can see here</p> <p>12 that under -- under the scanning microscope there is a</p> <p>13 distinction between fractures at the rim and below the</p> <p>14 rim, but this distance is actually two human hair. It's</p> <p>15 all that region. There's the first bend. So that's</p> <p>16 what I would call the danger zone.</p> <p>17 Q. Okay. Did you see in your examination of these</p> <p>18 filters whether the manufacturing process for that</p> <p>19 chamfer was consistent throughout the G2s and the</p> <p>20 Recovery filters you saw, or were there differences?</p> <p>21 A. Well, I mean, I -- I looked at exemplars to do</p> <p>22 this, basically, so I could cut them and section them.</p> <p>23 So I looked at, I think, four, two G2s and two</p> <p>24 Recoverys, and they were all sharp, but I estimated</p> <p>25 between 5 and 15 microns.</p>	<p style="text-align: right;">Page 28</p> <p>1 wasn't. The fact is that it was this feature, which I</p> <p>2 think is a very important feature, was unset in the</p> <p>3 engineering drawings, and so it could be anything.</p> <p>4 Q. Well, that's kind of my point. Do you know</p> <p>5 whether it varied a whole lot in manufacturing or</p> <p>6 whether it was pretty consistent to fall within 5 to</p> <p>7 15 --</p> <p>8 A. Well, I don't -- I don't know, I don't know.</p> <p>9 But, I mean, being unset anything could happen, right,</p> <p>10 so you'd have to look at a lot more than four filters to</p> <p>11 make that decision, but I don't know.</p> <p>12 Q. Now, does the G2-X or G2-Express have the same</p> <p>13 chamfer?</p> <p>14 A. The Express -- I've only looked at one Express,</p> <p>15 but that looked a little bit different. It has a sort</p> <p>16 of a 45-degree section. I have a picture of it here if</p> <p>17 I can find it. It's still not perfect because the edges</p> <p>18 are still unset, but it's, certainly to my way of</p> <p>19 thinking, a better feature. Yes, you can see it there.</p> <p>20 Now, I only looked at one. I looked at the Milton,</p> <p>21 which is Express, right, you have --</p> <p>22 Q. Right.</p> <p>23 A. So you can see there --</p> <p>24 Q. What page are you on?</p> <p>25 A. I'm on Page 20, Figure 25.</p>
<p style="text-align: right;">Page 27</p> <p>1 And then your expert, Fashing, got upset and</p> <p>2 said it was 10. As far as I, know it varied, because it</p> <p>3 was unset. There was nothing in the engineering</p> <p>4 drawings apart from the early ones that specified what</p> <p>5 that chamfer should be.</p> <p>6 Q. Was there anything above 15 that you saw?</p> <p>7 A. Not that I saw. But, you know, my population</p> <p>8 was very small. I looked at four exemplars, so I didn't</p> <p>9 do an exhaustive study on every valve, because to get a</p> <p>10 good -- you need to section the --</p> <p>11 Q. Right.</p> <p>12 A. -- and I couldn't do that with the ones --</p> <p>13 Q. So were you able to tell on the non-exemplar</p> <p>14 ones and the retrieved ones what the radius of the edge</p> <p>15 was?</p> <p>16 A. Well, the problem is, to get a decent reading,</p> <p>17 you need to section them, and that would be conceived as</p> <p>18 -- perceived as destructive.</p> <p>19 Q. Yeah. So you have -- you have no data that</p> <p>20 tells you that the retrieved filters that you saw were</p> <p>21 anything different from the 5 to 15 microns on that</p> <p>22 edge.</p> <p>23 A. I have no information that says they were</p> <p>24 larger or smaller. I didn't look at that point. But my</p> <p>25 particular point here is not the fact that it was or it</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. All right. Let me get there with you. Yeah.</p> <p>2 A. And you see they cut a 45 -- looks like a 45</p> <p>3 degree. But there's an edge there. It's not the nicest</p> <p>4 detail from a perspective of -- you could still get</p> <p>5 stress concentrations at that lower edge, but,</p> <p>6 nevertheless, I think it's an improvement.</p> <p>7 Q. All right, and how -- how much of an</p> <p>8 improvement is it? What would you estimate that edge</p> <p>9 is?</p> <p>10 A. Well, again, it would depend on the radius of</p> <p>11 that lower rate. I don't know exactly what that is.</p> <p>12 With a -- with an unset chamfer, the elevation of the</p> <p>13 stresses is unbanded. It could be infinite, basically.</p> <p>14 And so it depends on the radius. And so -- I haven't</p> <p>15 done these calculations because McMeeking did these</p> <p>16 calculations, and he was able to come up with numbers</p> <p>17 quite significant.</p> <p>18 MR. DALIMONTE: So just for the record, for</p> <p>19 clarification, it's -- Figure 25, I think in response to</p> <p>20 your question what page.</p> <p>21 MS. DALY: Yeah.</p> <p>22 MR. DALIMONTE: You said 25.</p> <p>23 MS. DALY: 20 I mean.</p> <p>24 MR. DALIMONTE: Page 20, figure 25.</p> <p>25 Q. (By Ms. Daly) So in order to actually</p>

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<p style="text-align: right;">Page 30</p> <p>1 determine what you determined for the G2 and Recoverys, 2 which was that radius being somewhere between 5 and 15 3 microns, to determine that for G2-Express you would have 4 to get an exemplar and you'd have to cut into it, right? 5 A. Well, you could sort of ballpark it, but, yes, 6 you really need to do a section. And I have a picture 7 of one here. That kind of thing. You see? 8 Q. Yeah. 9 A. You can then get a good reading of the radius. 10 Q. And the higher the microns for radius? 11 A. The lower the -- lower the stress. 12 Q. Lower the strain. 13 A. No. Stress concentrations. 14 Q. Stress concentrations. 15 A. Now, remember, these are what's called elastic 16 stress concentrations, and if they -- if they exceed the 17 yield strength of the material, then -- then you don't 18 get the full effect. So when you do a calculation like 19 McMeeking did, in some of these you got factors of ten 20 times the stresses.. You wouldn't necessarily see that, 21 because it would cause local yielding. But it's -- 22 Q. Well, do you know that Dr. McMeeking didn't 23 consider the chamfer in the G2-Express, but the 24 calculations he did -- 25 A. No, I'm talking in general. Stress</p>	<p style="text-align: right;">Page 32</p> <p>1 world has fractured at that point. 2 A. No. 3 Q. Okay. 4 A. See, my -- I've only looked at theory, two 5 G2-Expresses, so my statistics are a little bit -- 6 Q. Right. And on the Seale one, you're not 7 showing any fracture at the rim. 8 A. No, it's the more common one that occurs just 9 within a couple hundred microns. 10 Q. Okay. So based on the Seale one or the Molten 11 one, you don't have an example of one that is likely to 12 have fractured at the chamfer; is that fair? 13 A. Yes. I mean, just as -- I mean, I think you're 14 -- you're on the edge of the field of the chamfer, in 15 the hundred microns, but I would think that because 16 you're on the edge of that, I don't think the chamfer 17 itself -- presence of the rim is important, but the 18 chamfer itself is probably less important in those 19 Express cases. 20 Q. All right. In your -- in your report, it's 21 actually at Page 5, top paragraph, 22 A. Yes. I have to tell you something about that. 23 There's one typo in this report. 24 Q. Okay. 25 A. Right here.</p>
<p style="text-align: right;">Page 31</p> <p>1 concentrations are elastic there. They're bad news. 2 They're very localized. But they can lead to 3 plasticity, which is something that deforms, and that 4 creates tea cracks. 5 Q. My simple question on the G2-Express is that 6 you have not seen an exemplar to be able to do a 7 cut-down to know what the modification of the chamfer 8 was, correct? 9 A. Yes. 10 Q. And you do not know that Dr. McMeeking has done 11 that, McMeeking has done that. 12 A. As far as I know. I don't know. He wouldn't 13 have looked at that; I would have looked at that. 14 Q. So that is, to be honest, an unknown for you, 15 correct? 16 MR. DALIMONTE: Well, objection. 17 THE DEPONENT: I'm going to say -- all I'm 18 saying is the sharp edge is a nasty design detail. In 19 the G2-Express they have made some attempt to rectify 20 that issue, and it certainly would have improved the 21 situation, but it hasn't resolved it totally because 22 there's still an edge there. But I don't have exact 23 details, so -- 24 Q. (By Ms. Daly) Okay, but having seen one 25 G2-Express, you don't know if any G2-Express in the</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. If you look down to like the fourth from the -- 2 from the bottom sentence above Figure 2? 3 A. Yes. 4 Q. It says: 5 "The G2-Express with retrievable hook added 6 to the cap and small differences to the 7 shape of this cap." 8 Were you talking about the chamfer area or 9 something in addition? 10 A. I mean, it's not -- it's the form of this here, 11 but it doesn't -- 12 Q. The form of the cap as shown in Figure 2? 13 A. That's a general statement, so the chamfer was 14 different; I made my point. But the cap looks like it 15 as well. 16 Q. Is there -- do you have any opinion that the 17 change in the cap either increased the possibility of a 18 fracture or decreased it, or you're neutral on that? 19 A. I'm neutral on that. Just while we're here, 20 there's a -- I think this is where -- there's a comment 21 on here about -- well, yes. It says at top of Page 3, 22 fourth line down, it says the Eclipse cleared by the FDA 23 in 2008. That should be 2010. 24 Q. Yeah, all right. 25 A. And there's another reference to that on Page</p>

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Page 34	<p>1 24, which should be 2010 as well.</p> <p>2 Q. All right. Now, you have not done any bench</p> <p>3 testing in the course of your work in this litigation of</p> <p>4 any Bard filter, true?</p> <p>5 A. True.</p> <p>6 Q. And you've not tried to do any bench testing</p> <p>7 that compares, you know, how does the Recovery do versus</p> <p>8 the G2 or the G2 --</p> <p>9 A. No, I have not done anything.</p> <p>10 Q. Now, that, that kind of testing is something</p> <p>11 you have done in your career?</p> <p>12 A. Oh, yeah, I mean, not necessarily with -- I've</p> <p>13 looked at certain medical devices, but I haven't done</p> <p>14 bench testing on that. I don't have pulse duplicators</p> <p>15 and stuff, but I've certainly looked at those things,</p> <p>16 yes.</p> <p>17 Q. What kind of testing have you -- have you done?</p> <p>18 A. Well, I'm a person that studies the mechanical</p> <p>19 properties of materials and how they fail and so forth.</p> <p>20 And so most of my testing are what's known as coupon</p> <p>21 testing, where I get the properties of the material</p> <p>22 occasionally when it's forced to test the actual</p> <p>23 component.</p> <p>24 But, quite frankly, for understanding</p> <p>25 properties, that's -- that's not the best way to go.</p>	Page 36	<p>1 MR. DALIMONTE: Oh. And what did you want him</p> <p>2 to read?</p> <p>3 MS. DALY: Let me take this back for a second.</p> <p>4 He was talking about --</p> <p>5 MR. DALIMONTE: Well, what line?</p> <p>6 MS. DALY: I'm looking for it. If you look</p> <p>7 starting at Line 8, he was talking about things he'd</p> <p>8 done in the past, the type of testing, and through what</p> <p>9 I'm going to ask him --</p> <p>10 MR. DALIMONTE: Hold on --</p> <p>11 MS. DALY: Hold on. I'm going to ask him about</p> <p>12 through 13.</p> <p>13 MR. DALIMONTE: Read through Line 8 through</p> <p>14 Line 13?</p> <p>15 MS. DALY: No, through Page 13.</p> <p>16 MR. DALIMONTE: Oh, okay.</p> <p>17 MS. DALY: Line 4.</p> <p>18 MR. DALIMONTE: Okay. Let me read it, please.</p> <p>19 (Reviewing.) You want the question before?</p> <p>20 MS. DALY: I just want him to -- I'm happy to</p> <p>21 read it, but this is what he said he had done about</p> <p>22 testing before, and I just wanted to ask him to look at</p> <p>23 that and agree whether that testimony is correct for the</p> <p>24 type of testing that he's done in the past.</p> <p>25 MR. DALIMONTE: Yeah, hold on a second. Let me</p>
Page 35	<p>1 It's more important from the perspective of if you can</p> <p>2 design a widget you want it to operate and work. But</p> <p>3 I'm more at the other end of the fundamental end trying</p> <p>4 to understand what the property materials are and so</p> <p>5 forth.</p> <p>6 Q. I wanted to show you this Ocasio, because this</p> <p>7 is what you've said about the tests you did before, and</p> <p>8 just get you to confirm this is what you've done in the</p> <p>9 past. This is from your -- you recall coming live to</p> <p>10 give testimony in a Florida case called Ocasio?</p> <p>11 A. Yes.</p> <p>12 MS. DALY: Okay, I'm going to make this No. 6.</p> <p>13 (Whereupon, Exhibit 6 was</p> <p>14 marked for identification.)</p> <p>15 Q. It's falling off the back a little bit, but I</p> <p>16 wanted you to look at that and then see Page 12. Then</p> <p>17 look at Page 12, is what I wanted you to do.</p> <p>18 A. Okay. So --</p> <p>19 MR. DALIMONTE: Hold on a second.</p> <p>20 MS. DALY: Because I want to let him look at</p> <p>21 that, and then I want to just read it for one second and</p> <p>22 get you to comment on it, okay?</p> <p>23 MR. DALIMONTE: Hold on a second. Page 6, you</p> <p>24 said?</p> <p>25 MS. DALY: No, 12.</p>	Page 37	<p>1 read it. (Reviewing.) Okay.</p> <p>2 THE DEPONENT: So I've studied fatigue for 49</p> <p>3 years, and I think I've tested -- I think I've fatigued</p> <p>4 virtually every material on the planet. That's,</p> <p>5 obviously, not true, but a host of metals, bones,</p> <p>6 plastics, composites and what have you. That's my</p> <p>7 forte. And if you can look on the web, I think I'm the</p> <p>8 most quoted person in fatigue of craft publication</p> <p>9 issues.</p> <p>10 So I got involved in Nitinol in probably the</p> <p>11 late '70s, early '80s, and I was funded by people like</p> <p>12 Cortis and NDC, and I've done a lot of work on fatigue.</p> <p>13 So my situation has generally been to a number of</p> <p>14 things. I'm interested in mechanisms, why things fail,</p> <p>15 why things deform. And I'm also interested in trying to</p> <p>16 devise life prediction strategies, particularly medical</p> <p>17 devices, and I did this for heart valves; I've done it</p> <p>18 for stints. I haven't done it for filters, but --</p> <p>19 Q. But you have done it on Nitinol.</p> <p>20 A. Of course. I've worked on Nitinol basically</p> <p>21 since the late '70s.</p> <p>22 Q. And is that fatigue, fatigue testing that you</p> <p>23 set up a protocol for it and you do it in a lab with a</p> <p>24 machine?</p> <p>25 A. Yes. I have -- I have a lot of testing</p>

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<p style="text-align: right;">Page 38</p> <p>1 machines, and we do it under various conditions, 2 different frequencies, different environments and so 3 forth, so -- 4 Q. So it's something you're very familiar with 5 doing. 6 A. Absolutely. 7 Q. Whether you have a grad student standing at a 8 machine -- 9 A. I used to do it myself in the early days. 10 Q. Okay. So the only point I was making out of 11 that was in this litigation you have not done that kind 12 of lab failure testing on a Bard product. 13 A. No. The only things I've done, I've looked at 14 the failures and I've tried to understand why they 15 failed. But I have not done specific testing on Bard 16 products. 17 Q. All right. Very good. Going forward to the 18 Eclipse filter -- 19 A. Yes. 20 Q. Have you seen one, whether an exemplar or a 21 retrieved one? 22 A. No. 23 Q. Do you know what the chamfer radius is on an 24 Eclipse? 25 A. No.</p>	<p style="text-align: right;">Page 40</p> <p>1 Eclipse failure, you do not know that chamfer causes 2 failures in Eclipses. 3 MR. DALIMONTE: Objection. 4 THE DEPONENT: I mean, I don't -- I -- I don't 5 know. I have not. 6 Q. (By Ms. Daly) Okay. Now, same thing I'm going 7 to ask you about Meridian and Denali, same questions. 8 Have you seen a Meridian? 9 A. No. 10 Q. Have you looked at a design file? 11 A. Yes, I've looked at the design file. 12 Q. Okay. Have you seen any SEM photographs that 13 Dr. Fashing has done of a Meridian? 14 A. No, I don't think she has -- the reports that I 15 have, I have not seen one. 16 Q. Have you -- have you seen a Denali? 17 A. No. 18 Q. Have you seen the design history files for 19 those? 20 A. I've skimmed those reports. 21 Q. All right. For either the Meridian or the 22 Denali -- well, let's start with the Meridian. For the 23 Meridian, do you know what the chamfer radius situation 24 is? 25 A. No.</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. Have you looked at the design history file or 2 510K submission for that? 3 A. I haven't looked at the 515K submission; I've 4 looked at the earlier file you talked about, and I've 5 looked at various images of the Eclipse, particularly 6 some of the pictures that Fashing took. She -- she -- 7 she's like me, has only looked at very few Eclipses -- 8 I'm sorry, very few Expresses, but she had looked at one 9 Eclipses. And I certainly looked at those, yes. 10 Q. You looked at her pictures? 11 A. Yes. 12 Q. Are you able to tell from her pictures of that 13 one Eclipse what the chamfer -- 14 A. I don't think there's a picture of that. I was 15 more interested in that of the surface condition of the 16 wires. 17 Q. And we'll get to that, but -- so similar to 18 what you just answered for me on the G2-X, you have not 19 been able -- you have not taken an Eclipse filter, cut 20 it open and actually measured the chamfer. 21 A. I've never seen the Eclipse. 22 Q. So you do not know what it is, as far as -- 23 A. No. 24 Q. All right. And so therefore you do not know, 25 because of that and also because you haven't seen an</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Okay. So, again, for that one you can not say 2 that a chamfer issue is causing fractures in that 3 picture. 4 A. That's true. 5 Q. Do you know if the Denali even has a chamfer? 6 A. No, it's a different -- it's a laser cut thing, 7 so I don't know the chamfer is an issue there. 8 Q. All right, so no chamfer -- no chamfer 9 contributing to fracture in Denali. 10 A. Yeah. 11 Q. Because it doesn't have one. 12 MR. DALIMONTE: Can we take a quick break, get 13 some water? 14 VIDEOGRAPHER: We're off the record at 10:54 15 a.m. 16 (Recess) 17 VIDEOGRAPHER: We're back on the record. The 18 time is 10:58 a.m. 19 MS. DALY: You can just set that one aside; 20 pieces are coming off a little. Yeah. 21 Q. I'm going next to Page 6 of your report. What 22 I want to talk to you about next is your opinion that in 23 many devices poor surface conditions promote initiation 24 of fatigue cracks, okay? 25 A. Yes.</p>

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<p style="text-align: right;">Page 42</p> <p>1 Q. Page 6 is talking about that from the 2 standpoint of Recovery filters. All right? Are you 3 with me? 4 A. Yes. 5 Q. You note that in 12 -- in all 12 of the 6 Recovery filters and the exemplar that you examined, 7 they showed evidence of preexisting, pre-implant surface 8 damage, correct? 9 A. Yes. 10 Q. How many of the Recovery filters which are on 11 Page 2 of the chart that was previously identified as 12 Exhibit 5, how many of those had fractures that 13 initiated at or because of a surface condition? 14 A. Well, it's difficult to answer that question 15 precisely, but I can say that of the Recovery filters 16 there's one exception. One failed, up, further up the 17 leg, but virtually all failed in the feet region. And 18 they failed -- I can only -- you can almost 19 categorically state they failed because the cracks were 20 initiated and the grinding marks that were left where 21 they tapered the -- the hook there. 22 Q. Okay. And that's another opinion I'm going to 23 go to next. 24 A. Yes. 25 Q. So setting aside the foot fractures --</p>	<p style="text-align: right;">Page 44</p> <p>1 is that a foot fracture only? 2 A. No, there was one -- there was an arm fracture. 3 Q. Okay. 4 A. I mean, that's -- that column, crack-initiated 5 defect, fall under the global column of failed arms. 6 Q. So all those are arms I just read off. 7 A. You know, my feeling was, essentially, looking 8 at the Recovery is that virtually 100%, but there is one 9 leg there on a stall where they failed in the foot 10 region. They all failed in the foot region. 11 Q. So -- so, let me be sure I'm clear. So the 12 ones that you think initiated at a surface defect that 13 were not feet -- 14 A. Yes. 15 Q. -- they were arms, was Gray, maybe Lynch, 16 Newton, Roble and Mata. 17 A. That's right. 18 Q. All right. Can -- do surface conditions that 19 initiate fracture initiate them locally? 20 A. Yes. I mean -- let me just explain that the 21 material doesn't know where the stress or strain is 22 coming from, right, so it just reacts to what it sees. 23 And I talk about global stresses or strains, and if you 24 bend something, you put a global stress on it. But 25 there are -- local phenomenon and stress concentrations</p>
<p style="text-align: right;">Page 43</p> <p>1 A. Yes. 2 Q. -- were there any leg or arm fractures that you 3 could associate with a specific surface anomaly, 4 condition, whatever? 5 A. Well, it's difficult to see after the fact 6 sometimes, because you might be looking -- there's 7 fractures in two places and maybe the defect was on the 8 bit you don't see. But of the ones I looked at, I've 9 got a column here that says "initiated at a defect." 10 And in those, those situations, it's reasonably clear, 11 it's not a hundred percent, always, but the cracks -- 12 the initiation of the crack seemed to be associated with 13 defect. So when you look at the edge of the fractured 14 surface, you can see some sort of marking or defect. 15 And you'd expect that, of course, because any defect, 16 it's a local stress concentration that starts the crack 17 propagating. So -- 18 Q. So the ones you've listed with that column are 19 the Gray filter, Lynch with a question mark. 20 A. The Lynch is not quite certain. 21 Q. Okay. Newton. 22 A. Yeah. 23 Q. Roble. 24 A. Yeah, and Mata. 25 Q. And Mata. Now, with respect to Gray, though,</p>	<p style="text-align: right;">Page 45</p> <p>1 are the main reason for that. And this is the plague of 2 aircraft and anything. 3 Q. And this is a very simplistic question, but say 4 you've got a gouge mark on an arm. 5 A. Yes. 6 Q. That is not going to translate into a strain 7 that causes a fracture in a leg. 8 A. No. 9 Q. It would be local to that arm. 10 A. I mean -- and I said earlier, you know, they're 11 pretty localized, and typically whatever the radius of 12 curvature of that defect is, it's typically within two, 13 two radii. It would feel -- the material would feel the 14 effect of that stress concentration. 15 Q. All right. 16 A. That's, of course, why any technique which 17 smooths the surface, like electropolishing, is highly 18 beneficial. 19 Q. Now, in your G2s, same question. If we look at 20 the chart, which of the G2s could you associate a 21 non-foot fracture with a surface condition? 22 A. Well, again this -- the -- they may have all 23 gotten that way, but in terms of what one can see and a 24 reasonable assessment of a crack and a defect in the 25 Carnehl and the Moore, one of the Moores, the cracks</p>

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<p style="text-align: right;">Page 46</p> <p>1 seemed to initiate exactly at a defect.</p> <p>2 In a failure analysis, that's the holy grail.</p> <p>3 If you can trace the crack back to some origin and you</p> <p>4 can find a defect there, then that makes a strong case.</p> <p>5 You can't always do that.</p> <p>6 Q. So perhaps in Carnehl.</p> <p>7 A. Yeah.</p> <p>8 Q. That would be one of the contributors.</p> <p>9 A. I think that was a pretty good -- in the first</p> <p>10 Moore.</p> <p>11 Q. In the first Moore.</p> <p>12 A. Yeah. I have some pictures of these somewhere,</p> <p>13 here, if you can find them.</p> <p>14 Q. Okay. Now, in looking at -- let's stick with</p> <p>15 Recovery filters for a minute, the Recovery filters that</p> <p>16 were retrieved and the exemplar you looked at --</p> <p>17 A. Yes.</p> <p>18 Q. Would -- obviously, the surface conditions are</p> <p>19 never going to be exactly the same, right?</p> <p>20 A. Yes, uh-huh.</p> <p>21 Q. Did you see much variation filter to filter</p> <p>22 that would tell you there was a large manufacturing</p> <p>23 variation?</p> <p>24 A. No, I didn't see that. There was a lot -- a</p> <p>25 lot of the surface damage which could have been removed,</p>	<p style="text-align: right;">Page 48</p> <p>1 well.</p> <p>2 Q. Okay, can you give me an example of a G2 that</p> <p>3 shows that phenomenon?</p> <p>4 A. Yeah, hopefully. Yeah, it's not a particularly</p> <p>5 great picture, but on Page 16, specifically Figure 19,</p> <p>6 the crack in that particular arm appears to be</p> <p>7 associated with one of those gadgets. And there are</p> <p>8 other examples, but that one that comes up.</p> <p>9 Q. So in the G2s, that's the Carnehl that you</p> <p>10 already told us --</p> <p>11 A. Yes.</p> <p>12 Q. -- you thought was a surface condition.</p> <p>13 A. Yes.</p> <p>14 Q. Can you look at your Moore 1 and G2 and tell me</p> <p>15 whether you think you see a gouge there as opposed to a</p> <p>16 different kind of --</p> <p>17 A. Okay, let me just see what I'm doing here. So</p> <p>18 this is -- this is not -- Moore is a G2, right? Is it?</p> <p>19 Q. This one has Moore 51 and Moore 43.</p> <p>20 A. And they're G2s, though, right?</p> <p>21 Q. Yeah, they're G2s.</p> <p>22 A. Okay, just give me a second here. I'll go</p> <p>23 through. Okay, G2s, here we go. Moore, right. Okay.</p> <p>24 Here we go, Moore. Yeah, well, that's -- I mean, that's</p> <p>25 -- again, the pictures don't come out really well here,</p>
<p style="text-align: right;">Page 47</p> <p>1 but I didn't see masses. Again, my population was not</p> <p>2 that great, but the sort of damage you see is -- you</p> <p>3 call it typical.</p> <p>4 Q. Okay, fairly consistent.</p> <p>5 A. Uh-huh.</p> <p>6 Q. Okay. And in the G2-Express that you did</p> <p>7 examine, two of them, what can you tell me about the</p> <p>8 surface condition of those? Was there any difference?</p> <p>9 A. No, it looked pretty much the same, actually.</p> <p>10 There was no -- the Express, that's right. It was</p> <p>11 pretty much the same.</p> <p>12 Q. And you did not get to see an exemplar on the</p> <p>13 Express, right?</p> <p>14 A. No.</p> <p>15 Q. I think you noted in your report that you saw</p> <p>16 on the Recovery filter some gouging that you didn't</p> <p>17 typically see in the G2s. Do you remember that?</p> <p>18 A. Yeah, I -- that was an earlier report. I think</p> <p>19 -- certainly the original Recoverys there was -- there's</p> <p>20 this sort of dent, looks like, which is in the knee of</p> <p>21 the first bend where the failures often occur, and that</p> <p>22 to me was where they shape-set it. They put it on a rig</p> <p>23 and fit it to form the shape. And initially I thought</p> <p>24 that was more of a problem with the Recoverys, but I'm</p> <p>25 not sure it is. It's quite a load of that on the G2s as</p>	<p style="text-align: right;">Page 49</p> <p>1 but that's --</p> <p>2 Q. We're looking at Page 84, Figure A2-6.</p> <p>3 A. Yeah.</p> <p>4 Q. Okay. Do you see a gouge in that leading to</p> <p>5 the Moore one?</p> <p>6 A. Yeah, well, there's -- there's -- you can see</p> <p>7 the surface here.</p> <p>8 Q. Uh-huh.</p> <p>9 A. It's kind of rough and so forth. There's a bit</p> <p>10 of debris there as well.</p> <p>11 Q. But -- but I'm asking, is that -- is that a</p> <p>12 similar type of gouge --</p> <p>13 A. Yes, I think so.</p> <p>14 Q. Okay. So in those two examples, you saw a</p> <p>15 similar gouge to what you --</p> <p>16 A. Yeah, you can see them here, in that region.</p> <p>17 Q. Okay. Now we're looking at Figure A2-8.</p> <p>18 A. Yeah.</p> <p>19 Q. All right. Very good.</p> <p>20 A. And they're -- they're -- I refer to different</p> <p>21 types of surface, but those are the gouges they talk</p> <p>22 about, and I think some of those were a result of the</p> <p>23 manufacturing process, the shape-setting, specifically.</p> <p>24 Q. And then we've talked about this before, your</p> <p>25 section on crack initiation, whether it's outside to</p>

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<p style="text-align: right;">Page 50</p> <p>1 inside or inside to out.</p> <p>2 A. Uh-huh.</p> <p>3 Q. And they were about roughly equal for whether</p> <p>4 it was inside-out or outside-in?</p> <p>5 A. In the G2s they're more outside-in, but in the</p> <p>6 Recoverys they're generally pretty well balanced.</p> <p>7 Q. And what is -- what opinion do you hold about</p> <p>8 the factors that caused that that give you the</p> <p>9 outside-in versus the inside-out? Is there anything you</p> <p>10 can point to that would have it start one way or the</p> <p>11 other?</p> <p>12 A. Well, I mean, one can never be certain about</p> <p>13 this, but my -- my -- when you see this kind of</p> <p>14 scenario, when you have a device which is -- or</p> <p>15 component which is -- and the cracks are growing in</p> <p>16 different directions, it generally means the component</p> <p>17 is experiencing different functionalities. And I think</p> <p>18 what we understand now is that if the arms or the legs</p> <p>19 are moving freely within the vena cava, then you can</p> <p>20 generate certain bending stresses which will be tensile</p> <p>21 or compressive on one side of the -- of the wire.</p> <p>22 But if these -- these arms or wires get, you</p> <p>23 know, etheralized to the wall, if they perforate, then</p> <p>24 that's going to radically change the stress state. And</p> <p>25 that's what I felt initially, that there was a change in</p>	<p style="text-align: right;">Page 52</p> <p>1 A. No.</p> <p>2 Q. Is there any way that you can look at a -- at</p> <p>3 any of the fractures in these cases and say, "That was</p> <p>4 contributed to by amount of clot that came into that</p> <p>5 filter"?</p> <p>6 MR. DALIMONTE: Objection.</p> <p>7 THE DEPONENT: I mean, you might be able to do</p> <p>8 it from other techniques, but by looking at the fracture</p> <p>9 surface, you wouldn't.</p> <p>10 Q. (By Ms. Daly) So you're not going to give that</p> <p>11 opinion?</p> <p>12 A. No -- there -- there are multiple sources for</p> <p>13 fatigue and there are multiple reasons why these cracks</p> <p>14 formed.</p> <p>15 Q. Right.</p> <p>16 A. Some may have played a bigger role in some</p> <p>17 cases than others, but certainly by looking at the</p> <p>18 fractography of the surface you couldn't tell whether a</p> <p>19 clot caused it or --</p> <p>20 Q. And I just want to be clear that when you get</p> <p>21 up at trial you're not going to say in any of these</p> <p>22 Bellweather cases, for example --</p> <p>23 MR. DALIMONTE: Objection. This deposition</p> <p>24 isn't about the Bellweather case; it's about his</p> <p>25 opinions on the MDL.</p>
<p style="text-align: right;">Page 51</p> <p>1 the function of the device. Again, people like</p> <p>2 McMeeking have done calculations which suggest there is</p> <p>3 this change of a stressed state, and I think that's</p> <p>4 perfectly reasonable, and I think that's the reason.</p> <p>5 So in some of these cases -- and it's difficult</p> <p>6 to be precise, because we don't know what was happening</p> <p>7 in the body; we look at it afterwards. But maybe one of</p> <p>8 these wires perforated and that caused the stress state</p> <p>9 to change. So that -- that's my opinion.</p> <p>10 It also could be that there could be defects</p> <p>11 that we can't see on the back, but defects are fairly</p> <p>12 small, localized, rather. I think the main factor here,</p> <p>13 whether the crack goes this way or this way, is due to</p> <p>14 the global stresses and what the filter's doing.</p> <p>15 Q. And we're going to talk about perforation in a</p> <p>16 minute, because that's also a column on the chart which</p> <p>17 is Exhibit 5.</p> <p>18 A. Yeah.</p> <p>19 Q. So you talked about perforation a little bit.</p> <p>20 Is -- is there any work that you have done that you can</p> <p>21 say, "I can tell you by the type of fracture I've seen</p> <p>22 on the ones I've examined that that filter was in a tilt</p> <p>23 situation"?</p> <p>24 A. By looking at the fracture surface?</p> <p>25 Q. Right.</p>	<p style="text-align: right;">Page 53</p> <p>1 MS. DALY: Right. I'll rephrase it.</p> <p>2 Q. In any case that goes to trial in the MDL,</p> <p>3 based on what you've submitted right now -- and if you</p> <p>4 do future work, that's fine, but based on what you've</p> <p>5 presented today, you are not going to testify that in a</p> <p>6 case X, "I can tell you that that fracture was a result</p> <p>7 of perforation of so much tilt, of so much clot burn, of</p> <p>8 so much" -- you have not done that work.</p> <p>9 A. That is not quite the question asked me. You</p> <p>10 asked me based on the fractography of looking at</p> <p>11 fractured surfaces.</p> <p>12 Q. Let's start there.</p> <p>13 A. You can't do that.</p> <p>14 Q. Okay.</p> <p>15 A. But certainly there can be -- if, in a</p> <p>16 hypothetical case, you had CT scans of a person that had</p> <p>17 a filter in for a long period of time and you could</p> <p>18 follow whether a perforated strut subsequently broke,</p> <p>19 then you could, for example, have direct evidence that</p> <p>20 the perforation would have led to the fracture. So</p> <p>21 that's -- that's an important distinction, but you don't</p> <p>22 get that information by looking at the fracture surface.</p> <p>23 Q. Okay, and what -- what you just described one</p> <p>24 could do with looking at imaging and so on, have you, as</p> <p>25 one person, done that --</p>

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<p style="text-align: right;">Page 54</p> <p>1 A. Yes.</p> <p>2 Q. -- in any case? Okay, which cases have you</p> <p>3 done that for?</p> <p>4 A. Well, this is one of those new cases you're</p> <p>5 talking about, right?</p> <p>6 MR. DALIMONTE: Well --</p> <p>7 MS. DALY: The reports are due today. If he's</p> <p>8 done it, let's just say. Then I'll leave that to the</p> <p>9 next deposition.</p> <p>10 MR. DALIMONTE: Yeah, I would leave that to the</p> <p>11 next deposition --</p> <p>12 MS. DALY: But I --</p> <p>13 MR. DALIMONTE: On the Bellweather.</p> <p>14 MS. DALY: That's fine.</p> <p>15 Q. Have you done that in any cases?</p> <p>16 A. I made a point, actually, in -- in the</p> <p>17 rebuttal, in that I've been very anxious to try and show</p> <p>18 that perforation can lead to fracture. It seems</p> <p>19 blatantly obvious that it should. It seems, on the</p> <p>20 basis of McMeeking's calculations, it clearly should.</p> <p>21 The fact that the cracks grow in different directions in</p> <p>22 these wires indicates there's a change of function. So</p> <p>23 everything points to that.</p> <p>24 But when you look at the fracture after the</p> <p>25 fact, you don't know which -- which wire is perforating,</p>	<p style="text-align: right;">Page 56</p> <p>1 MR. DALIMONTE: So --</p> <p>2 MR. DALIMONTE: Booker.</p> <p>3 Q. (By Ms. Daly) Booker, okay, thank you. And</p> <p>4 you'll get to see the filter on that one.</p> <p>5 A. That would be -- that would be really nice.</p> <p>6 Q. Okay, all right.</p> <p>7 A. Because Dr. Fashing had said there's no direct</p> <p>8 evidence between perforation and fractures, so this does</p> <p>9 provide compelling evidence; it's an obvious thing.</p> <p>10 Q. In one case.</p> <p>11 A. Of course.</p> <p>12 Q. Okay.</p> <p>13 A. As I said in my rebuttal, it's damn dangerous</p> <p>14 leaving these things in there --</p> <p>15 Q. That's nonresponsive. Please, let's just let</p> <p>16 me go to the next thing.</p> <p>17 Okay, so continuing on on the surface</p> <p>18 conditions --</p> <p>19 A. Yes.</p> <p>20 Q. -- opinions, I'm moving now to Eclipse.</p> <p>21 A. Yes.</p> <p>22 Q. Have you examined the surface of an Eclipse,</p> <p>23 exemplar?</p> <p>24 A. I have not seen an Eclipse, so the only -- the</p> <p>25 only observations that I've made on the surface</p>
<p style="text-align: right;">Page 55</p> <p>1 which is not. But in some of the more recent cases</p> <p>2 which you'll see in this report, there's one in</p> <p>3 particular where the filter was in that person for a</p> <p>4 long period of time, five, six, seven or eight years,</p> <p>5 and she had a series of CT scans. The interventional</p> <p>6 cardiologist was able to point to specific struts which</p> <p>7 perforated and then subsequently fractured.</p> <p>8 And so in those cases, I think -- to my way of</p> <p>9 thinking, this provides me with a bit of direct proof</p> <p>10 that perforation -- again, it's not looking at the</p> <p>11 fracture surface --</p> <p>12 Q. I understand.</p> <p>13 A. -- looking at something else.</p> <p>14 Q. So you -- you have put in a report as of today</p> <p>15 in one case with doing that analysis?</p> <p>16 A. There's two cases. I can't remember what the</p> <p>17 other one is. But one of the five being submitted</p> <p>18 today. But one is particularly persuasive because the</p> <p>19 filter was in such a long time.</p> <p>20 Q. Which case is that?</p> <p>21 MR. DALIMONTE: Well, why don't we wait?</p> <p>22 MS. DALY: No. Your reports are due today.</p> <p>23 Can I just know which one he's doing? I mean, your</p> <p>24 reports are due today, for heaven's sake. And we gave</p> <p>25 you an extension of time.</p>	<p style="text-align: right;">Page 57</p> <p>1 condition of the Eclipse are based on about four or five</p> <p>2 photographs in a recent report by Dr. Fashing.</p> <p>3 Q. Okay. Why did you not examine one?</p> <p>4 A. I was not sent one.</p> <p>5 MR. DALIMONTE: Oh, Objection.</p> <p>6 MS. DALY: Why are you objecting to that?</p> <p>7 MR. DALIMONTE: Well, because there's a -- a</p> <p>8 set of requests for documents where exemplars were</p> <p>9 supposed to be produced by Bard for each of the</p> <p>10 iterations, and they have yet to produce them. So we</p> <p>11 can't send them to --</p> <p>12 MS. DALY: Oh, my heavens.</p> <p>13 MR. DALIMONTE: -- experts until you</p> <p>14 produce --</p> <p>15 MS. DALY: Oh, my heavens --</p> <p>16 MR. DALIMONTE: -- those exemplars.</p> <p>17 Q. (By Ms. Daly) Okay, so you asked your attorney</p> <p>18 to get you an exemplar.</p> <p>19 A. I would like to have seen them.</p> <p>20 Q. Okay. And you haven't seen them for whatever</p> <p>21 reason, the lawyers will work that out, but you haven't</p> <p>22 seen one.</p> <p>23 MR. DALIMONTE: Well, first of all, no, no.</p> <p>24 You're not going to ask him questions, anything that</p> <p>25 we've discussed.</p>

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<p style="text-align: right;">Page 58</p> <p>1 MS. DALY: I didn't. I said "You haven't 2 gotten one, correct?"</p> <p>3 MR. DALIMONTE: Okay, that's different, but you 4 said you asked your lawyer -- you asked the lawyers, is 5 what you said. Anyway, just move on.</p> <p>6 MS. DALY: Okay --</p> <p>7 MR. DALIMONTE: Just move on.</p> <p>8 Q. (By Ms. Daly) You haven't seen an Eclipse, a 9 Denali or a Meridian.</p> <p>10 A. Correct.</p> <p>11 Q. All right. Did you understand that the court 12 had given an extension of time to experts to put in a 13 specific report about Denali and Meridian?</p> <p>14 A. Yes, I did.</p> <p>15 Q. Okay. And did you want to see an exemplar for 16 Meridian and Denali?</p> <p>17 A. I would like to have, but, remember, I'm a 18 fracture person and I've never seen any fractures of 19 these components. But certainly it would be nice to see 20 those things. You can see the files which has the 21 statistics of fractures, so if you knew what that was, 22 even though you're not looking at your own ones, that 23 would be something useful to have, definitely.</p> <p>24 Q. Yes.</p> <p>25 A. But I don't have that.</p>	<p style="text-align: right;">Page 60</p> <p>1 MR. DALIMONTE: Move on. We don't have to have 2 this colloquy on the record.</p> <p>3 MS. DALY: We probably need to take that up 4 with the court so we know where we're going on those 5 filters, so we don't have late -- we don't have late 6 provided information from these experts.</p> <p>7 Q. Okay, so surface conditions -- going back, 8 because you have not seen and have not examined under 9 SEM or any other way, an Eclipse, a Meridian or Denali, 10 you can not testify about what the precise surface 11 conditions are. True?</p> <p>12 A. I've seen pictures of the Express -- sorry, the 13 Eclipse --</p> <p>14 Q. The Eclipse, okay.</p> <p>15 A. And that's -- and that's -- that's all I have 16 at this point.</p> <p>17 Q. And how does the surface look to you based on 18 Dr. Fashing's SEM of the Eclipse?</p> <p>19 A. Well, again, it's a little bit arbitrary, but, 20 as you know, the Eclipse is electropolished, and there 21 is certainly evidence still of inclusions; there has 22 been evidence of the circumferential markings and draw 23 markings, but they are much smoother than they ever were 24 prior, in the previous filters.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. Well, for the record --</p> <p>2 MR. DALIMONTE: Well, for the record, too, in 3 clarification of Professor Ritchie's statement, he 4 hasn't seen cases -- specific cases haven't been 5 evaluated by him.</p> <p>6 MS. DALY: I understand that --</p> <p>7 MR. DALIMONTE: But it doesn't mean they don't 8 exist.</p> <p>9 MS. DALY: I understand that, but I want to put 10 this on the record. So Mr. Dalimonte is saying that 11 experts, including you and Mr. McMeeking, have not seen 12 exemplars of the Eclipse, the Meridian or Denali because 13 somehow we failed to answer a request for production, 14 which you have filed no motion to compel on; you have 15 not done a meet and confer on to say, "We don't have 16 them." You have an MDL that includes, at your request, 17 Eclipse, Meridian and Denali. The court gave you extra 18 time to do Meridian and Denali. You did not ask about 19 exemplars. Is that your position, that it's our fault?</p> <p>20 MR. DALIMONTE: You were required to produce 21 them.</p> <p>22 MS. DALY: Yeah.</p> <p>23 MR. DALIMONTE: You haven't.</p> <p>24 MS. DALY: You've heard of the rules of civil 25 procedure?</p>	<p style="text-align: right;">Page 61</p> <p>1 A. So the electropolishing would certainly -- 2 these -- these -- these parts still may fail in the same 3 location, from what I gather is true, but -- in that 4 same sort of regions, but the presence of defects there 5 certainly is vastly improved by that question.</p> <p>6 Q. And can you -- based on just seeing pictures 7 from one Eclipse, are you able to say the extent to 8 which that improvement will provide fracture resistance 9 in an Eclipse?</p> <p>10 A. To put a number on it, of course, no. It would 11 certainly alleviate or tend to -- act to alleviate one 12 of the problems with the filters, but, no, you don't 13 need to have a defect to form a crack if you have a 14 large enough stress and so forth. There are many 15 reasons why these cracks form, but the role of defects 16 and certainly the circumferential grinding marks in the 17 foot seem to have been improved by the presence of 18 electropolishing.</p> <p>19 Q. All right. So you are not -- because you 20 haven't seen any and you haven't seen an exemplar of 21 Eclipse, is it fair to say that you can not say if any 22 fractured Eclipse out there in the world is related to 23 surface conditions?</p> <p>24 MR. DALIMONTE: Objection.</p> <p>25 THE DEPONENT: Well, I couldn't anyway. That's</p>

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<p style="text-align: right;">Page 62</p> <p>1 too broad a question. But I've looked at the fracture 2 files, the statistics of the various fractures, and 3 there isn't -- the Denali I'm not too certain was, but 4 there's an alarming similarity about where these things 5 tend to fail. 6 Q. (By Ms. Daly) Okay, and I'm not -- but I'm not 7 asking that; I'm asking -- 8 A. That's pertinent. We talked about local 9 effects like the chamfers and so forth. But the fact is 10 that if you identify the surface condition, the 11 electropolishing -- and this has been known for decades 12 -- would certainly improve the fatigue resistance. So 13 it would -- likely if you measured the fatigue limit it 14 would slightly increase it, but that doesn't guarantee, 15 of course, that there'd be no fatigue fractures -- 16 Q. Right. 17 A. -- but that aspect would be an improvement. 18 Q. An improvement. All right. And Meridian 19 carried forward with that electropolishing, true? 20 A. Yes. 21 Q. Do you know if there was any improvements in 22 the electropolishing process itself from the time -- by 23 Bard, from the time the Eclipse was first marketed 24 through when the Meridian has been marketed? 25 A. I -- I have not seen any evidence of that. I</p>	<p style="text-align: right;">Page 64</p> <p>1 Dr. Hearst. 2 Q. Right. 3 A. So in that respect I have looked at that, yes. 4 Q. Okay. And in some of the medical literature 5 you've looked at, were there descriptions or discussions 6 of types of fracture in the Eclipse, or just the fact 7 that a leg broke or an arm broke? 8 A. Well, I mean, there's a lot of medical issues, 9 so I can't say for certain there's nothing, but I doubt 10 it, quite frankly, because most of it's based on 11 radiology or CT scans, and that just tells you whether 12 something's separate, or its location. It couldn't 13 really tell you much about how it failed. 14 Q. And same question for Meridian. Did you look 15 at any literature specific to failures in a Meridian 16 filter? 17 A. I've looked -- I've seen the fracture files 18 that list the statistics and where they break and so 19 forth, and these are updated, as you know. I've not 20 seen any specific reports of fracture. I've not 21 examined any myself. 22 Q. What do you mean, "fracture files"? Are you 23 talking, about MAUDE data? 24 MR. DALIMONTE: Bard. 25 THE DEPONENT: The Bard statistics --</p>
<p style="text-align: right;">Page 63</p> <p>1 I don't know the answer to that question. 2 Q. Do you know one way or the other? 3 A. I don't know one way or the other. 4 Q. Okay. Then Denali, is that electropolished? 5 A. It's a laser cut. It's built like a stint, 6 basically, and I'm -- I'm actually -- I'm not certain. 7 I can't remember whether it was electropolished or not. 8 The need for electropolishing the Denali would be less, 9 you know, less imperative than in a wire one, but I 10 honestly don't -- I can't remember exactly whether it 11 was. It's a similar design, but it's a very different 12 animal by the way it's made. 13 Q. Right. Have you reviewed any medical 14 literature about failures in Eclipse filters 15 specifically? 16 A. Yes, and that again pertains to these five 17 cases that are being submitted today. 18 Q. One is an Eclipse? 19 A. There's two, I believe. 20 Q. I think there's one. 21 A. Whatever. And I've been sent all the medical 22 records. It a little difficult for people like me to 23 interpret medical records, so most of the time I've 24 looked at them and then I've relied on the -- the 25 interventional cardiologist reports, these reports by a</p>	<p style="text-align: right;">Page 65</p> <p>1 MR. DALIMONTE: Fracture history file -- 2 fracture analysis, the monthly fracture -- 3 THE DEPONENT: I have a whole slew of those. 4 Q. (By Ms. Daly) And those just tell you 5 generally location -- 6 A. Yeah, but -- but, you know, there's an alarming 7 similarity, if you look over the history that -- you 8 know, in the Recovery, the legs and feet, and there was 9 some in the G2s that went further up the legs. And then 10 if you look at the arm fractures, they -- they sort of 11 mirror the statistics in some respects. 12 Q. Well -- 13 A. You know, they have a much bigger population 14 than I do, but if you look at those pictures over the 15 years, the arm fractures still seem to occur in that 16 region just below the sheath. 17 Q. Okay, but you've seen no pictures of a fracture 18 of a Meridian. 19 A. No. 20 Q. Other than Dr. Fashing's pictures of the one 21 Eclipse, you haven't seen pictures of those, true? 22 A. Not -- I've -- like I've said, the only -- the 23 -- I've seen the pictures of Dr. Fashing's examination 24 of an Eclipse, and I've read -- I've -- I've -- the 25 medical files and interpretation of medical files for</p>

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<p style="text-align: right;">Page 66</p> <p>1 two Eclipse fractures.</p> <p>2 Q. What Bard documents have you read that give you</p> <p>3 any information about locations of fractures in either</p> <p>4 Eclipse, Meridian or Denali?</p> <p>5 MR. DALIMONTE: Objection; asked and answered.</p> <p>6 THE DEPONENT: Those are those Bard injury</p> <p>7 fracture files, and they -- they tend to give number of</p> <p>8 units sold and fractures or various adverse conditions.</p> <p>9 Q. (By Ms. Daly) But not like you've done; it</p> <p>10 won't say so many microns from the --</p> <p>11 A. No, not, but it -- it shows a picture of the</p> <p>12 filter, you know, and it says that X failed up here and</p> <p>13 Y failed down there. So, again, it sort of mirrors the</p> <p>14 general locations. I mean, what I found fascinating was</p> <p>15 that, you know, throughout this whole sequence of</p> <p>16 Recovery G2 and the various different G2s, the failure</p> <p>17 modes were remarkably similar in terms of their general</p> <p>18 location.</p> <p>19 Q. Is the Bard documents that you're just</p> <p>20 referring to about these locations of fractures, are</p> <p>21 they referenced in your report that we've marked 2?</p> <p>22 A. No, I don't think they're specifically</p> <p>23 referenced. I think they're probably listed as</p> <p>24 something I looked up. I didn't talk about them</p> <p>25 directly.</p>	<p style="text-align: right;">Page 68</p> <p>1 MR. DALIMONTE: Or I can give them to you, no</p> <p>2 problem.</p> <p>3 MS. DALY: All right, that's good. I probably</p> <p>4 don't want them all. I probably -- I just need the</p> <p>5 Bates ranges.</p> <p>6 Q. Okay. Did you review the 2016 publication by</p> <p>7 Dr. Stavoropolis and others on the results -- the final</p> <p>8 study results for the Denali and what the outcomes were</p> <p>9 there?</p> <p>10 A. I didn't.</p> <p>11 Q. So do you know that he reported zero fractures</p> <p>12 of the Denali in that article?</p> <p>13 A. No, I don't.</p> <p>14 MR. DALIMONTE: Well, the Denali hasn't been on</p> <p>15 the market very long.</p> <p>16 MS. DALY: Excuse me, John, that's not an</p> <p>17 objection, okay; it's not an objection.</p> <p>18 MR. DALIMONTE: Sorry. Just a silly question,</p> <p>19 that's all.</p> <p>20 THE DEPONENT: It's funny, because when you</p> <p>21 look at these Bard fracture reports, they're</p> <p>22 cumulative --</p> <p>23 MR. DALIMONTE: Well, don't volunteer any</p> <p>24 information unless you're asked a question.</p> <p>25 Q. (By Ms. Daly) You haven't looked at</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. Okay. For our next deposition, can you find</p> <p>2 for me the document before our next deposition? Can you</p> <p>3 find for me the document you're talking, about?</p> <p>4 MR. DALIMONTE: Yeah, it's the complete --</p> <p>5 THE DEPONENT: What are they called, the</p> <p>6 Bard --</p> <p>7 MR. DALIMONTE: They're -- they're Bard</p> <p>8 fracture analysis reports. They were monthly. They go</p> <p>9 back to the Recovery -- they didn't do them monthly on</p> <p>10 the Recovery, but they go back as far as 2004.</p> <p>11 MS. DALY: I'm just a little confused, because</p> <p>12 I don't -- I can't sum it up in my head that we did</p> <p>13 fracture reports that have pictures showing --</p> <p>14 MR. DALIMONTE: Hold on. Andre Chandusko. One</p> <p>15 of the exhibits is a complete binder. At that time, the</p> <p>16 latest report that we had was January 2013. Bard has</p> <p>17 since produced an updated file that goes to May 2016,</p> <p>18 and they're monthly, and they have a picture of a filter</p> <p>19 and they have a count of how many leg failures occurred</p> <p>20 at the chamfer versus elsewhere, versus the hook. And</p> <p>21 there were numbers.</p> <p>22 MS. DALY: If you would help me, because I want</p> <p>23 to know what he relied on. So before his next</p> <p>24 deposition, if you would give me the Bates ranges of</p> <p>25 what he relied on for that.</p>	<p style="text-align: right;">Page 69</p> <p>1 Dr. Stavoropolis' study which was the clinical trial of</p> <p>2 the Denali filter.</p> <p>3 A. Yes -- no, I haven't.</p> <p>4 Q. Okay. Now, you have examined -- have you --</p> <p>5 I'm sorry, have you examined a Simon Nitinol filter?</p> <p>6 A. No.</p> <p>7 Q. Have you looked at a design history file for a</p> <p>8 Simon Nitinol filter?</p> <p>9 A. Yes, I've read about it and so forth.</p> <p>10 Q. Have you done that recently?</p> <p>11 A. Yeah. I've done it some time ago. I'm looked</p> <p>12 at it, actually, reading some of it last night.</p> <p>13 Q. Okay. And I notice you have examined some Cook</p> <p>14 filters.</p> <p>15 A. Yes.</p> <p>16 Q. Recently.</p> <p>17 A. Well, over the last year-and-a-half.</p> <p>18 Q. Okay. And I know that you have submitted a</p> <p>19 report on the Cook filters. I know that, but obviously</p> <p>20 I'm have not seen the report. Okay. Is there -- are</p> <p>21 there any other manufacturers of IVC filters that you</p> <p>22 have personally been able to examine?</p> <p>23 A. No.</p> <p>24 Q. I'm not going to ask you what the comparison is</p> <p>25 or what the finding is. Have you done a side-by-side</p>

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<p style="text-align: right;">Page 70</p> <p>1 comparison of Bard Cook filters?</p> <p>2 A. What do you mean by "side-by-side"?</p> <p>3 Q. Looking at features to see if this one has this</p> <p>4 feature, this one has this feature and that area is</p> <p>5 different.</p> <p>6 A. Well, indirectly, yeah. I haven't done a -- I</p> <p>7 haven't done a precise, you know, back-to-back study,</p> <p>8 but, you know, I can -- you can see various different</p> <p>9 features in one that you don't see in others. They're</p> <p>10 -- they're nominally similar designs, but they're</p> <p>11 different animals, of course.</p> <p>12 Q. Do any of the Cook filters that you looked at</p> <p>13 have electropolished surfaces?</p> <p>14 A. They're a different material. I can't recall</p> <p>15 now. I can't recall. But they -- they -- I would say</p> <p>16 that they were cleaner, but it's a different material,</p> <p>17 so that's sort of a little bit of an imprecise. But I</p> <p>18 can't remember if they were electropolished or not.</p> <p>19 Q. All right, let's talk about centerless grind on</p> <p>20 the feet. All right, you -- you have an opinion you've</p> <p>21 given many times that the centerless grind on feet was a</p> <p>22 contributor to fracture of those feet.</p> <p>23 A. Yes. I'm mean, I'm think that's fair.</p> <p>24 Q. And you've listed on your chart -- we just</p> <p>25 talked about it -- those filters that have feet</p>	<p style="text-align: right;">Page 72</p> <p>1 again, let's go to the Recovery filters first. In those</p> <p>2 filters that you looked at, most of them had foot</p> <p>3 fractures.</p> <p>4 A. Yes, indeed.</p> <p>5 Q. If we go, then, to the G2 group --</p> <p>6 A. Yes.</p> <p>7 Q. -- which is a larger number of filters that you</p> <p>8 looked at, correct?</p> <p>9 A. Yes.</p> <p>10 Q. There are an ankle --</p> <p>11 A. And leg fractures, yes.</p> <p>12 Q. Okay, there's an ankle fracture, and then</p> <p>13 you've got a foot in the Carnehl case and two feet in</p> <p>14 Beckfield.</p> <p>15 A. Yes.</p> <p>16 Q. Correct?</p> <p>17 A. Yes.</p> <p>18 Q. Now, if I'm right and Beckfield is a Recovery</p> <p>19 filter; we'll find that out, you would only have found a</p> <p>20 fractured foot in Carnehl and maybe Shutter, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. You recall that in the G2 filter a</p> <p>23 modification that was made was to make the wires</p> <p>24 slightly larger?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 71</p> <p>1 breaking.</p> <p>2 A. Yes, I've used a distinction, foot versus leg,</p> <p>3 right.</p> <p>4 Q. In every instance of a broken foot, was it at</p> <p>5 the centerless grind area, if you recall?</p> <p>6 A. In the foot. There's one ankle -- I just</p> <p>7 noticed there's one ankle that may have been slightly</p> <p>8 away. I don't quite know, but it's in the shutter.</p> <p>9 I'll have to look at that. But virtually all of them</p> <p>10 failed in that sort of tapered -- remember, it's tapered</p> <p>11 so there's a thinner section.</p> <p>12 Q. And you call the ankle the part just above --</p> <p>13 A. Just above. So there's a change in radius</p> <p>14 there, so that, of course, does lead to a stress</p> <p>15 concentration, but nothing I think to the tune of what</p> <p>16 you'd have with the sharp grinding.</p> <p>17 Q. So the one ankle fracture you just mentioned</p> <p>18 was in the Shutter case. For the court reporter, it's</p> <p>19 S-h-u-t-t-e-r.</p> <p>20 A. Yes, I should look at that. And I think, if I</p> <p>21 recall, it was just a little further up.</p> <p>22 Q. So, yeah, you're welcome to look at that, and</p> <p>23 then I wanted you --</p> <p>24 A. Well, you can talk to me.</p> <p>25 Q. Okay. So looking at your chart, Exhibit 5</p>	<p style="text-align: right;">Page 73</p> <p>1 Q. Is it your understanding that that wire</p> <p>2 contributed to improving resistance to foot fracture for</p> <p>3 the G2s?</p> <p>4 A. It may have. It's -- I mean, it -- it's very</p> <p>5 difficult to say precisely, but certainly if it's</p> <p>6 slightly thicker, then the stresses may be somewhat</p> <p>7 lower.</p> <p>8 Q. So it may have improved --</p> <p>9 A. It may have improved, and that may have driven</p> <p>10 the fracture a little further up the leg. But certainly</p> <p>11 the -- there's a distinct difference between the -- at</p> <p>12 least on the basis of what I've looked at, between the</p> <p>13 leg fractures and the G2 and the Recovery, in that</p> <p>14 they're -- you don't see this evidence of the legs</p> <p>15 breaking further up. So the fact that the hook was</p> <p>16 perhaps thicker down there may have driven the fractures</p> <p>17 up.</p> <p>18 Q. Do you know -- what would you rely on to tell</p> <p>19 me, if that's the case?</p> <p>20 A. It's very difficult to do it. You'd have to do</p> <p>21 a pretty sophisticated calculation and you'd have to</p> <p>22 know exactly what the function of these filters are. A</p> <p>23 lot of the failures are a result of their adverse</p> <p>24 function; they tilt, they move and so forth, and so it's</p> <p>25 a difficult calculation to do precisely.</p>

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Page 75	<p>1 to the fracture in that location, but if you -- if you</p> <p>2 improve that location and it breaks somewhere else just</p> <p>3 up the road, basically, then you haven't gained much.</p> <p>4 But certainly, yes.</p> <p>5 Q. And again, with either the Eclipse, the</p> <p>6 Meridian, the Denali, you've done no work to determine</p> <p>7 how that modification a foot may have improved fracture</p> <p>8 resistance in the leg or --</p> <p>9 MR. DALIMONTE: Objection.</p> <p>10 Q. (By Ms. Daly) True?</p> <p>11 A. Well, the -- as I said, the only thing I've</p> <p>12 done is I've looked at these Bard fracture analysis</p> <p>13 reports and, again, they're general, right, but the</p> <p>14 locations of fractures are remarkably similar, and the</p> <p>15 general -- and the general locations of the leg in the</p> <p>16 foot versus in the mid-range of the -- of the leg and in</p> <p>17 the arm at the rim and just below the rim. And so</p> <p>18 that's -- that's a consist -- not so much Denali, but</p> <p>19 that's the consistent path throughout.</p> <p>20 And a slight change -- as I said, when you go</p> <p>21 to the Recovery to G2, then there's evidence that foot</p> <p>22 fractures are found and not -- they're leg fractures</p> <p>23 further up the wire. But that -- so the trends are not</p> <p>24 that different. But I haven't looked specifically at</p> <p>25 any Eclipse or Meridian or Denali fractures or even</p>	Page 77	<p>1 discipline.</p> <p>2 THE DEPONENT: You can't really do that,</p> <p>3 actually, from that data. All they're giving you is a</p> <p>4 cumulative plan.</p> <p>5 Q. (By Ms. Daly) Right. So you haven't done</p> <p>6 that.</p> <p>7 A. As I said, again --</p> <p>8 Q. Wait. You haven't done that.</p> <p>9 A. I haven't done that.</p> <p>10 Q. Okay.</p> <p>11 A. But all I'm saying is that the -- the general</p> <p>12 locations of fractures of arms and legs are remarkably</p> <p>13 similar in all the G2s throughout -- I don't know about</p> <p>14 the Meridian, just the Denali. But they're remarkably</p> <p>15 similar. But, again, the statistics are slightly</p> <p>16 distorted by the cumulative nature of them.</p> <p>17 Q. And you've done nothing statistically to try to</p> <p>18 figure out incidence.</p> <p>19 A. I don't think I could do that for that data</p> <p>20 anyway.</p> <p>21 Q. Okay. Now, the centerless grind issues that</p> <p>22 you saw in the Recovery filter, let's start there. Was</p> <p>23 it pretty consistent what you were seeing -- again,</p> <p>24 understanding there's slight differences in the</p> <p>25 manufacturers, but were you seeing a fairly consistent</p>

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<p style="text-align: right;">Page 78</p> <p>1 method of centerless grind in the Recovery filters?</p> <p>2 A. Yes.</p> <p>3 Q. Then when we move to G2, albeit we've got the</p> <p>4 modified foot wire, were you again seeing similar</p> <p>5 process there?</p> <p>6 A. Yeah, I'd -- I'd -- again, to get -- you know,</p> <p>7 one of the questions would be how sharp are these things</p> <p>8 and how deep were they. One would really have to</p> <p>9 section them to look at that, and I couldn't do that, of</p> <p>10 course. But, yes, in a general assessment they looked</p> <p>11 identical.</p> <p>12 Q. Will you look back at your -- your report on</p> <p>13 Milton? Do you know where to find him in your report,</p> <p>14 or his filter?</p> <p>15 A. Milton, the Express?</p> <p>16 Q. Yeah, he's the only Express.</p> <p>17 A. Yes, it should be here. Okay.</p> <p>18 Q. Where were you finding him?</p> <p>19 A. Well, I've got a picture on Page 25.</p> <p>20 Q. All right. Were there any fractures in that</p> <p>21 filter, in Figure 25? Is that what it is?</p> <p>22 A. Page 21.</p> <p>23 Q. 21, Figure 26, all right. Were there any</p> <p>24 fractures in Milton?</p> <p>25 A. It doesn't look like there was, no.</p>	<p style="text-align: right;">Page 80</p> <p>1 use "prone."</p> <p>2 A. It's the same words.</p> <p>3 Q. Okay. Moving on beyond that sentence, you then</p> <p>4 say:</p> <p>5 "Additionally, when these failures" --</p> <p>6 meaning what you've said before, which I</p> <p>7 assume is tilt, migration:</p> <p>8 "Additionally, when these failures</p> <p>9 render the device unable to be</p> <p>10 removed, it creates an unacceptable</p> <p>11 situation of a device that is</p> <p>12 unusually prone to fracture remaining</p> <p>13 in the body."</p> <p>14 Right?</p> <p>15 A. Uh-huh.</p> <p>16 Q. You've said that.</p> <p>17 A. Yes.</p> <p>18 Q. All right. So are you giving any opinion in</p> <p>19 this case about when a filter is not retrievable?</p> <p>20 A. No -- well, I mean, that would be beyond my</p> <p>21 station. There's some obvious things you can say, but</p> <p>22 I'm not a medical person.</p> <p>23 Q. Are you of the opinion that Bard filters are</p> <p>24 prone or susceptible to not being retrievable? Do you</p> <p>25 hold that opinion?</p>
<p style="text-align: right;">Page 79</p> <p>1 Q. All right. All right, let's talk about another</p> <p>2 opinion that you hold. It's on your report, Page 2, and</p> <p>3 it's at the bottom of that first full paragraph, about</p> <p>4 seven lines up. It's a little Roman Numeral IV. Do you</p> <p>5 see it?</p> <p>6 MR. DALIMONTE: Page 22?</p> <p>7 Q. (By Ms. Daly) No, 2, Page 2, and it's in this</p> <p>8 big section here, on Page 2. There's a little 4.</p> <p>9 A. Oh, yeah.</p> <p>10 Q. All right? That's what I want to talk to you</p> <p>11 about next. All right, your opinion there was:</p> <p>12 "Filters are prone to tilting and</p> <p>13 migration which can cause</p> <p>14 perforation, significantly elevating</p> <p>15 stress, which promotes fracture."</p> <p>16 All right?</p> <p>17 A. Yes.</p> <p>18 Q. What do you mean when you use the term "prone"?</p> <p>19 A. Susceptible to. I mean -- and that's just</p> <p>20 based on the statistics of fracture that we've seen and</p> <p>21 the -- in fact, where there is medical records primarily</p> <p>22 where there's indications that these tilt, and they can</p> <p>23 move and migrate and so forth.</p> <p>24 Q. I want to know your definition of the term,</p> <p>25 because I notice you use "susceptible" sometimes and you</p>	<p style="text-align: right;">Page 81</p> <p>1 A. Well, again, on the basis of the cases that</p> <p>2 I've looked at, there are numerous cases where, because</p> <p>3 of fragmentation or etherealization and so forth that</p> <p>4 the medical reports give the impression that it can be</p> <p>5 difficult to retrieve them.</p> <p>6 Q. Okay.</p> <p>7 A. And retrieve parts of them -- maybe they're in</p> <p>8 dangerous situations, but I'm not a medical person, so I</p> <p>9 can't speak directly to that.</p> <p>10 Q. And you've done no -- you've made no attempt to</p> <p>11 try to statistically determine the percentage of Bard</p> <p>12 filters that can't be retrieved.</p> <p>13 A. No. I'm sure somebody has, but I have not.</p> <p>14 Q. I do not believe so.</p> <p>15 A. Really? Okay.</p> <p>16 Q. All right. Then you also gave an opinion on</p> <p>17 Page 4 of that report -- I'm sorry, it's back on -- it's</p> <p>18 back on Page 2, pardon me. It's the last sentence</p> <p>19 there. You say:</p> <p>20 "It's my opinion that these filter</p> <p>21 devices were defectively designed and</p> <p>22 manufactured, rendering them unsafe for</p> <p>23 implant to the human body."</p> <p>24 Do you see that?</p> <p>25 A. Yes.</p>

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<p style="text-align: right;">Page 82</p> <p>1 Q. Okay. Are you giving that opinion from a</p> <p>2 materials expert standpoint only and not from a medical</p> <p>3 standpoint?</p> <p>4 A. Well, it's -- it's, of course, my -- my</p> <p>5 education, it would be from a materials standpoint, but</p> <p>6 if something is lodged in the heart, it's not difficult</p> <p>7 to understand that. It might be a difficult thing to</p> <p>8 have medically, but obviously my statement is primarily</p> <p>9 -- well, let's say scientifically based on material</p> <p>10 science and engineering, and sort of commonplace, based</p> <p>11 on some sort of medical understanding.</p> <p>12 Q. Do you hold the opinion in any case in this</p> <p>13 litigation that the particular plaintiff should not have</p> <p>14 had that particular Bard filter? Are you going to give</p> <p>15 that opinion?</p> <p>16 A. No.</p> <p>17 Q. Let's talk about McMeeking for a moment --</p> <p>18 actually, let me back up and talk about a few other</p> <p>19 experts. You have referenced reading the Kessler,</p> <p>20 Eisenberg and Betensky reports.</p> <p>21 A. Yes.</p> <p>22 Q. Do you rely on those reports for anything in</p> <p>23 particular?</p> <p>24 A. No, they're background, basically. It's</p> <p>25 interesting to read the stories and so forth, but I</p>	<p style="text-align: right;">Page 84</p> <p>1 Let's talk about Dr. McMeeking for a moment, because I</p> <p>2 know you do rely on him, correct?</p> <p>3 A. Uh-huh.</p> <p>4 Q. All right. You say in this March 2 report</p> <p>5 that's Exhibit 2 --</p> <p>6 A. Yes.</p> <p>7 Q. You've said that you've read McMeeking's</p> <p>8 depositions; is that correct?</p> <p>9 A. Yes.</p> <p>10 Q. You've read his MDL reports.</p> <p>11 A. Well, I've read -- I'm -- I don't know how many</p> <p>12 he's written, but I've -- I read a recent one, yes.</p> <p>13 Q. Okay. So let's look at McMeeking's reports, if</p> <p>14 we could, and --</p> <p>15 A. I'm not sure I've been sent all the recent</p> <p>16 depositions. I've read the earlier ones, but certainly</p> <p>17 there's a recent report I've read which is the MDL</p> <p>18 report, I think.</p> <p>19 MR. DALIMONTE: Just one second. Once again,</p> <p>20 you were raising your hand.</p> <p>21 VIDEOGRAPHER: I had an itch.</p> <p>22 MR. DALIMONTE: Oh. Sorry.</p> <p>23 (Whereupon, Exhibits 7-9 were</p> <p>24 marked for identification.)</p> <p>25 Q. (By Ms. Daly) Okay, I'm going to first hand</p>
<p style="text-align: right;">Page 83</p> <p>1 don't -- I wouldn't say I don't rely on them, but</p> <p>2 they're more of a background to me.</p> <p>3 Q. There is no specific statement or opinion or</p> <p>4 data they have in those reports that is essential to you</p> <p>5 in giving your opinions in the case?</p> <p>6 MR. DALIMONTE: Objection.</p> <p>7 THE DEPONENT: It's difficult to say. I mean,</p> <p>8 I would hate to rule it out, but, I mean, some of the</p> <p>9 discussion of how some of the tests were done and how</p> <p>10 some of the -- mirror and give more detail than I</p> <p>11 originally understood before I read them, so there's a</p> <p>12 lot of background information there.</p> <p>13 I'm not concerned about the politics and how</p> <p>14 they dealt with the FDA; that's not in my area. But</p> <p>15 certainly how the tests were done, what was -- what was</p> <p>16 looked at, what wasn't looked at, they have a bearing,</p> <p>17 yes. And I'm --</p> <p>18 Q. Have you --</p> <p>19 MR. DALIMONTE: Hold on. Let him finish.</p> <p>20 Q. (By Ms. Daly) I'm sorry.</p> <p>21 A. I mean -- but, I mean, I think -- as you know,</p> <p>22 I think Bard was somewhat gung ho in their approach to</p> <p>23 the design of these devices and the testing they did,</p> <p>24 and I think that's amplified in those reports.</p> <p>25 Q. We'll talk about testing in another section.</p>	<p style="text-align: right;">Page 85</p> <p>1 you what's Exhibit 7, which is a McMeeking report dated</p> <p>2 March 3rd of 17.</p> <p>3 A. Most of this is --</p> <p>4 MR. DALIMONTE: I want to make sure it's the</p> <p>5 same document I'm referring to.</p> <p>6 THE DEPONENT: It's thicker than I have.</p> <p>7 Q. (By Ms. Daly) And then I'm going to show you</p> <p>8 what I've marked as 8, which is his supplementary report</p> <p>9 assessing Meridian and Denali dated April 7th, 2007.</p> <p>10 And then I'm going to give you 9, which is his</p> <p>11 rebuttal report in the MDL dated May 11th, 2017. Just</p> <p>12 take a minute to look at those and tell me which of</p> <p>13 those you have studied, reviewed, studied, whatever you</p> <p>14 want to call it.</p> <p>15 A. I haven't seen the rebuttal report.</p> <p>16 Q. All right.</p> <p>17 A. These -- these look somewhat different to what</p> <p>18 I've seen, but they contain a lot of the same</p> <p>19 information.</p> <p>20 Q. Okay. So you think you've seen Exhibit 7,</p> <p>21 which is -- I'll tell you, it's his general MDL report.</p> <p>22 A. Yeah, but there's a lot of mathematics in here</p> <p>23 that was not in my version, so I think -- I don't know</p> <p>24 what that is.</p> <p>25 Q. So you may not have seen his final MDL one, is</p>

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Page 86	<p>1 what you're saying.</p> <p>2 A. I don't know.</p> <p>3 Q. All right.</p> <p>4 A. I don't think I've seen this one, the</p> <p>5 supplementary report, but I've seen a lot of -- I've</p> <p>6 seen a lot of this, but there's details in here that</p> <p>7 were not in the version that I saw.</p> <p>8 Q. All right. So you don't believe that you've</p> <p>9 seen Exhibit 8, which is his supplementary report in the</p> <p>10 MDL on Meridian and Denali, April 7th, 2017.</p> <p>11 A. I don't think so.</p> <p>12 Q. Okay. Have you seen Exhibit 9, which is his</p> <p>13 rebuttal report, May 11, 2017?</p> <p>14 A. No.</p> <p>15 Q. All right. Let's just put those there for a</p> <p>16 minute and work off this, work off this one, which is</p> <p>17 Exhibit 7.</p> <p>18 MR. DALIMONTE: This might be a good breaking</p> <p>19 point, before we get into this report. It's noon. We</p> <p>20 can go off the record.</p> <p>21 VIDEOGRAPHER: We're off the record at 11:57.</p> <p>22 This is the end of Disk No. 1.</p> <p>23 (Recess)</p> <p>24 VIDEOGRAPHER: We're back on the record. This</p> <p>25 marks the beginning of Disk No. 2 in the deposition of</p>	Page 88	<p>1 you do rely on some of his work?</p> <p>2 A. Yes -- well, let me just say that what I try to</p> <p>3 do is understand why fractures took place, and look at</p> <p>4 -- look at the -- hopefully look at the actual part and</p> <p>5 see how it failed, sort of trying to decipher why things</p> <p>6 failed when it did with the defects present and so</p> <p>7 forth.</p> <p>8 What McMeeking does is he does calculations,</p> <p>9 and so the advantage of that is that you start to get</p> <p>10 some numbers, right, so you -- so, for example, you can</p> <p>11 say this had an effect, but with some numbers you can</p> <p>12 get some quantification of that effect. That's what's</p> <p>13 very useful about this.</p> <p>14 Q. So did you rely on that?</p> <p>15 A. Well, I mean, it impacts upon my opinions. For</p> <p>16 example, I believe that when you perforate a strut, that</p> <p>17 the likelihood of fracture is increased. That seems</p> <p>18 intuitively obvious to me. And McMeeking's calculations</p> <p>19 will then show actually the stresses are raised by the</p> <p>20 perforation. So that's consistent with my -- that's the</p> <p>21 way I use it.</p> <p>22 Q. So let's take that as an example. So you have</p> <p>23 a hypothesis that perforation can lead to fracture.</p> <p>24 MR. DALIMONTE: Objection.</p> <p>25 THE DEPONENT: It's not really a hypothesis. I</p>
Page 87	<p>1 Robert O. Ritchie, Ph.D. The time is 12:42 p.m.</p> <p>2 Q. (By Ms. Daly) Doctor Ritchie, when we broke,</p> <p>3 we were talking about making reports, and just to recap,</p> <p>4 I think you said for the report marked as Exhibit 7,</p> <p>5 you've seen that, but maybe not the full one that's</p> <p>6 before you?</p> <p>7 A. Yeah, I'm not sure whether -- I've seen -- most</p> <p>8 of it's identical, but I didn't recognize some of the</p> <p>9 bits at the back. Maybe I didn't look at all the</p> <p>10 appendice, I'm not quite certain, but it's the report</p> <p>11 I've seen. I took out a lot of -- a lot of stuff here</p> <p>12 on this resume that I didn't -- it's the same report.</p> <p>13 Q. Okay, and then on Exhibit 8, which is his</p> <p>14 supplementary report on Meridian and Denali, April 7th?</p> <p>15 A. Yes, I -- I realize I have both those; 8 and 9</p> <p>16 I have.</p> <p>17 Q. Okay. You've had 8 and 9.</p> <p>18 A. Yes.</p> <p>19 Q. Okay. All right, I'm going to refer to those</p> <p>20 at times, so just keep those with you.</p> <p>21 A. Okay.</p> <p>22 Q. As I've said, you -- you noted several times in</p> <p>23 testimony or in your recent reports that you either</p> <p>24 adopt information from Dr. McMeeking's reports or you</p> <p>25 agree with it or you rely on it. Is that correct, that</p>	Page 89	<p>1 mean --</p> <p>2 Q. (By Ms. Daly) You said it was intuition.</p> <p>3 A. Well, okay, but, I mean, there's certain things</p> <p>4 that are intuitively obvious to me, and it's nice to get</p> <p>5 some confirmation, numerical confirmation. Nothing in</p> <p>6 engineering is, you know, 100% precise, but if you know</p> <p>7 that a certain feature or an event causes an elevation</p> <p>8 of a stress, that is completely consistent with the fact</p> <p>9 that -- okay, call it a hypothesis, say a hypothesis,</p> <p>10 that if you perforate a strut it's more likely to</p> <p>11 fracture.</p> <p>12 Q. Okay, so looking at it from what I want to look</p> <p>13 at it from, which is the science of how this was done,</p> <p>14 you have an opinion that fracture and perforation are</p> <p>15 associated, yes?</p> <p>16 A. They can be associated.</p> <p>17 Q. Okay. And what you relied on from McMeeking</p> <p>18 that is relevant to that is the calculations he does in</p> <p>19 his MDL reports about strains in a perforating filter.</p> <p>20 A. Well, I'm -- I mean, when you say "relied on,"</p> <p>21 it's a strong word. I mean, on the basis of the</p> <p>22 evidence that I see, and now I've seen it from the</p> <p>23 medical report, I'm almost certain that happens, and</p> <p>24 then a calculation is showing that's consistent with</p> <p>25 that. So if that's what you mean by "relied," then I</p>

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<p style="text-align: right;">Page 90</p> <p>1 relied. But I don't need that information to draw my 2 conclusion, but it's certainly consistent with that. 3 Q. Let's break that down. Was there something 4 from medical records that gave you some scientific 5 information or medical information that allowed you to 6 say that perforation is equated with fracture or -- 7 A. Well, as I said this morning, in many of the 8 cases where there are multiple perforations or many 9 perforations there often are fractures. And so you can 10 make the correlation that one led to the other, but 11 without knowing exactly that Strut No. 3 perforated and 12 Strut No. 3 fractured, it's difficult to make that 13 direct comparison. 14 And so now with some of the more detailed 15 intervention cardiologist reports where they can -- they 16 looked at each individual strut and watched it in 17 someone's body over a period of time -- I'm talking 18 about the Booker case now -- that that becomes more 19 definitive. And then so that, to me, is pretty 20 compelling proof that, in fact, that in -- when you have 21 a perforated strut, it can certainly fracture. Now -- 22 Q. Would you agree that it can certainly -- that 23 it can also not fracture when you have -- 24 A. Of course. There's a million things. You 25 know, you can die of cancer -- doesn't say you wouldn't</p>	<p style="text-align: right;">Page 92</p> <p>1 is certainly important information. 2 Q. So I want to separate these two things again. 3 I want to know what work you did and what work McMeeking 4 did, and what work of McMeeking's you must rely on to 5 come to your opinion. 6 I'm going to start again. You -- 7 MR. DALIMONTE: Objection; asked and answered. 8 THE DEPONENT: I mean, I'm -- 9 MR. DALIMONTE: He just explained it. 10 MS. DALY: No -- you know what, John, you did 11 this last time. I have him. You already are wasting my 12 time. I have seven hours with him. He is an expert. 13 He's been an expert in this litigation for years. I'm 14 am going to ask him every question I need until I'm 15 understand it, whether you like it or not. 16 MR. DALIMONTE: Then you can ask him -- 17 MS. DALY: Thank you. 18 MR. DALIMONTE: -- to explain. 19 MS. DALY: That's what I'm doing. 20 MR. DALIMONTE: You asked -- 21 MS. DALY: I can ask him -- 22 MR. DALIMONTE: -- same question and he 23 explained it, and I said it was asked and answered. 24 Q. (By Ms. Daly) Dr. Ritchie -- 25 MR. DALIMONTE: If you want a further</p>
<p style="text-align: right;">Page 91</p> <p>1 die of a heart attack in a different situation. 2 Q. Well -- 3 A. I mean, that's the point. You've got to 4 remember that -- I've heard this so many times, that 5 this thing didn't perforate but it still fractured, 6 therefore perforation is not associated with fracture. 7 Everything is synergistically interactive and, you know, 8 the worst case causes the eventual failure, so -- 9 Q. Okay, so is there any study out there that 10 you're aware of that looked at the association between 11 fracture and perforation? 12 A. Well, there are indirect studies that basically 13 show that there's so many perforations and so many 14 fractures. But to be absolutely certain, you have to 15 really focus on one particular strut that perforated, or 16 more than one strut and then subsequently fractured. 17 It seems intuitively obvious to anybody that if 18 you've got something wedged in there, it's constrained, 19 that's going to raise, raise the stresses. And that's 20 -- okay, it's not more than a hypothesis; it makes 21 sense. And that someone -- like when McMeeking has done 22 calculations, you know, they're done to a strong degree 23 of engineering certainty, but you don't know all the 24 details. But if, if indeed it shows that the stresses 25 are elevated and they're significantly manned, then that</p>	<p style="text-align: right;">Page 93</p> <p>1 explanation, then it's a -- when I object, then it's 2 because it's an issue related to form. 3 MS. DALY: You're wasting my time, and we've 4 already had two breaks and started at 10:00 o'clock. 5 So, please. 6 Q. Dr. Ritchie, I am interested in science because 7 that's what the court's going to be interested in, okay? 8 I want to know everything that you rely on to say that 9 perforation is related to fracture. Let's start with 10 that. 11 And if it's your intuition, that's fine, say 12 that. But I need to know every single thing that you 13 would even remotely testify about at trial in these 14 cases of why you think perforation leads to fracture. 15 A. With due respect, I think I've answered it, 16 but, I mean, first the -- the first, first issue is the 17 fact that the fracture surfaces indicate propagation in 18 different directions. 19 The second factor is that the constraint of any 20 wire will certainly elevate the stresses or strains, 21 particularly in the point where they fracture, which is 22 the pivot point where it comes out of the sheath. So 23 one would expect that to be a problem in terms of 24 elevating the stresses. 25 There is not quite anecdotal information, but</p>

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<p style="text-align: right;">Page 94</p> <p>1 there's information where there's been filters that have 2 had perforations and have also had fractures, and now we 3 have evidence where specific struts which are perforated 4 subsequently fracture. This is a pretty compelling 5 argument the two things are linked. 6 And now you look at some calculations and they 7 suggest what one would suspect in the first place, that 8 a perforated strut would have an elevated stress on it. 9 So that's the consistent picture of what you would say. 10 Q. Thank you. Does that information that you've 11 just recited allow you to know how often a perforating 12 strut will fracture? 13 A. No. 14 Q. Does it allow you to know what degree of 15 perforating strut will be the one that fractures? 16 MR. DALIMONTE: Objection. 17 THE DEPONENT: You mean how much it perforates? 18 Q. (By Ms. Daly) Correct. 19 A. Well, I'm sure those calculations could be 20 done. I haven't done them, of course. McMeeking may 21 have done them, I haven't seen them. But one could then 22 -- you could determine the degree of elevation of 23 stresses, but there's so many other factors, it's 24 difficult to do a calculation which, you know, takes 25 into account everything. So you have to talk in degrees</p>	<p style="text-align: right;">Page 96</p> <p>1 50 fractured filters came to them with no perforations 2 and half came with perforations. Are you familiar with 3 that? 4 A. Yeah, I've seen that study. 5 Q. Okay. So that study doesn't really provide us 6 with anything more than basically what you've just said, 7 that perforation and strut -- I mean perforation and 8 fracture can be seen in the same strut. 9 A. No. It's -- I mean, there's -- it could have 10 failed by some other reason prior to that. So you can't 11 say that. But, you know, that study is -- I wouldn't 12 say inconsistent, but it's not supportive, because 13 there's too many other things going on. And that's not 14 unusual in failure. 15 Q. And -- and let's go forward with that, because 16 you've said this multiple times to me in depositions and 17 you said it in your reports, that there is a complex 18 interaction of things going on in these filters that 19 will lead to any given complication, say fracture, tilt, 20 perforation; there's an interaction of things. 21 A. Well, I think -- yeah, it would be kind of 22 preposterous to think there wasn't. But there are -- 23 there are -- I guess that's not the right word, but 24 abnormal modes of operations of filter. It can tilt; it 25 can migrate; it can perforate. And those situations</p>
<p style="text-align: right;">Page 95</p> <p>1 of scientific certainty. It's not -- you can't be exact 2 on this. 3 Q. And so you -- you can't say whether it's more 4 probable than not that any -- 5 A. I didn't say that. 6 Q. Wait a minute. Let me ask my question, then 7 you can answer. 8 You can't say, within a reasonable engineering 9 certainty, that it's more probable than not that any 10 given perforating strut is going to fracture. 11 MR. DALIMONTE: Objection. 12 THE DEPONENT: Well, you know, you're trying to 13 box me into a situation where there are a myriad of 14 factors that are involved, and so they all contribute. 15 I can say that a perforated strut will -- will almost 16 certainly see a higher stress on it or strain on it, 17 which will make it more likely to fracture, but -- and 18 that's certainly more likely than not, but to actually 19 go one stage further and say just because it perforates 20 it will fracture, you can't say that. 21 Q. (By Ms. Daly) And let me -- let me point you 22 to a study that I think you're familiar with. It's a 23 study that Coe and Peterson -- I'm sorry, Robertson did 24 in 2014, I think, where, interestingly, in studying 25 fractures they had almost exactly half the -- half the</p>	<p style="text-align: right;">Page 97</p> <p>1 will certainly change its function and change the 2 stresses on it. 3 If, just by thinking about it in general terms 4 a lot of these things you'd expect to cause an elevation 5 of local stresses. The material doesn't care where the 6 stresses and strains come from. So that increases the 7 likelihood of some of the other events occurring. 8 Now, whether tilt precedes migration or 9 migration precedes tilt is -- is a -- sort of almost an 10 impossible question to answer. But certainly these 11 adverse modes are not the way the filter was intended to 12 operate. 13 And what McMeeking has done is he's looked at 14 each of these and given some estimate of numerically 15 now, or at least a quantitative estimate, of what that 16 might factor the stresses. And I don't care whether 17 it's a factor of -- you know, whether it goes from 35 to 18 36 or 35 to 38; it's giving a trend that's important, 19 because we can't know these things precisely when we 20 look at the actual things. 21 So that's how I like McMeeking's work, because 22 it gives a totally different analysis. I'm looking at 23 the part -- I'm looking at the failure, and he's doing a 24 calculation, and the results are consistent. And that's 25 the way that science is generally done.</p>

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<p style="text-align: right;">Page 98</p> <p>1 Q. Well, will you agree with me that there could 2 be literally millions of different configurations of 3 this filter in a person and -- 4 MR. DALIMONTE: Objection. 5 Q. (By Ms. Daly) -- let me give you thoughts on 6 that. So you've got 12 legs, right? You could have a 7 filter that was tilting from one degree to 180, I guess. 8 You could have two perforating legs that were side by 9 side. You could have two perforating legs that were at 10 12:00 o'clock and 6:00 o'clock, and any number of 11 combinations of that sort of thing. True? 12 A. Sure. 13 Q. So that a precise determination in a given 14 filter of what caused a fracture in that filter is, as 15 you've said, a complex thing to determine. True? 16 MR. DALIMONTE: Objection. 17 THE DEPONENT: Yeah, but you can say that if -- 18 you know, if one leg broke then the stresses on the 19 remaining legs would be elevated. You could say that if 20 the filter tilted, there would be an argument that you 21 could think that it might be more likely to penetrate. 22 And so there are -- there are very reasonable conclusive 23 statements that you can make. 24 Now, do you have hundred percent scientific 25 proof? Science is not like that; it's very rare you</p>	<p style="text-align: right;">Page 100</p> <p>1 A. This is -- every -- 2 Q. "Yes" or "no"? 3 A. I can't qualify that. Every fracture analysis 4 of everything that's ever failed, be it an aircraft, 5 it's no different. It's -- I mean, failures take place 6 because generally a multitude of events occur and -- 7 problems, be it design or material or defects or stress, 8 and so you have to put together a consistent picture. 9 It's very difficult to say that one failed because -- 10 that's just something not -- 11 Q. Yeah, I understand what you're saying, and my 12 point beyond that is that makes it very difficult. 13 A. I think it makes it easier, because if there 14 was one thing wrong with this filter you could say, 15 "Yes, because it perforated." But there's so many 16 things wrong with it that -- that you don't need to say 17 that. You know, there's always something there; there's 18 always some weak link there to cause it. 19 Q. But you don't know the probability for any 20 given filter or all filters to fracture or not; you 21 don't know the probability of that? 22 MR. DALIMONTE: Objection. 23 THE DEPONENT: Well, there's statistics -- 24 Q. (By Ms. Daly) That you don't do. 25 A. No, but I've read about them, and people have</p>
<p style="text-align: right;">Page 99</p> <p>1 have that. So you put together a picture and you hope 2 to get input from totally different sources. 3 And McMeeking's calculations are completely 4 different to what I do in looking at a fracture surface. 5 You know, there obviously has to be, in any normal of 6 engineering, some degree of idealization. You couldn't 7 look at every one of these scenarios; there's a million 8 scenarios; you've talked about it. But you can 9 certainly pick up general trends. 10 And the converse of this is it would be absurd 11 to think the fact that if a filter lost a leg that it 12 will be less likely to have an adverse -- one of these 13 adverse events. 14 Q. But it may or may not. 15 A. Well, of course, because it all depends on the 16 individual -- also the individual person, you know, the 17 stiffness of their vena cava and what they're doing. 18 But -- but, you know, this is -- this is a medical 19 device that's put into a lot of people, and therefore 20 one would expect it to function in a fashion that 21 wouldn't cause so much distress and problems. 22 Q. Well, this is what -- what you've just said 23 about the complexity of it makes a determination of the 24 probability of event one causing event two difficult to 25 predict.</p>	<p style="text-align: right;">Page 101</p> <p>1 looked at X number of filters that have ever been 2 implanted and find that X, Y percent failed by fracture, 3 and so there is that information which is the facts of 4 what has happened. But I look -- I'm at the other end 5 trying to understand. I know here -- 6 Q. You're not trying to -- 7 MR. DALIMONTE: Let him finish his -- 8 MS. DALY: It's hard, because he continues for 9 a long time. 10 MR. DALIMONTE: He's a professor. Let him 11 finish what he was going to say. 12 THE DEPONENT: I've forgotten. 13 Q. (By Ms. Daly) Your role in this case is not to 14 figure out the probability of that happening, though, is 15 it? 16 MR. DALIMONTE: Objection. 17 THE DEPONENT: Well, I -- I don't think that 18 people like stress analysts like McMeeking and a person 19 like myself can actually do that. I think the 20 probabilities of failure have to be based on the 21 postmortem effects of looking at these devices, this -- 22 we've got 60 devices here and 30 failed by this and 20 23 failed by that. That's where the statistics comes up. 24 That's almost impossible to predict. 25 (By Ms. Daly) All right. So -- so let me ask you a</p>

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<p style="text-align: right;">Page 102</p> <p>1 little bit more about McMeeking and reliance on him. In</p> <p>2 some past depositions you said, very candidly, "I have</p> <p>3 not attempted to verify what he's done."</p> <p>4 Have you done anything now that you verified</p> <p>5 assumptions that he made, verified calculations that he</p> <p>6 did?</p> <p>7 A. I wouldn't verify his calculations. I mean, he</p> <p>8 is probably the finest stress analyst on the planet.</p> <p>9 Q. How about verification of assumptions he used</p> <p>10 to put in?</p> <p>11 A. Oh, yeah, I will look at some of those. I</p> <p>12 mean, I've talked to him a little bit about what -- what</p> <p>13 he's assumed for fatigue limits, and some of the</p> <p>14 material properties we've talked about, but far be it</p> <p>15 for me to question his mechanics.</p> <p>16 Q. Yeah, so let's put mechanics to the side. So</p> <p>17 tell me what assumptions of his you have independently</p> <p>18 verified.</p> <p>19 A. Well, when we -- the main things have been on</p> <p>20 material properties. I mean, we've -- we've had a</p> <p>21 considerable problem understanding what BARD meant by</p> <p>22 their fatigue properties because of their impreciseness</p> <p>23 in quoting what they're measuring. So I've helped in</p> <p>24 that regard and given some information. I've written a</p> <p>25 lot of reports on this anyway, in the literature.</p>	<p style="text-align: right;">Page 104</p> <p>1 A. Yes, of course, of course.</p> <p>2 Q. Okay.</p> <p>3 A. I mean, we've worked together for a long time</p> <p>4 and this is how we operate. We've always done it that</p> <p>5 way.</p> <p>6 Q. Did you look to see if there was any literature</p> <p>7 out there that would lead you to believe that an</p> <p>8 assumption that Dr. McMeeking has used is inaccurate,</p> <p>9 for example, blood flow?</p> <p>10 A. Not a priority. I've looked -- I mean, some of</p> <p>11 the things that he's done I've looked at afterwards.</p> <p>12 I've been intrigued by -- for example, he has some</p> <p>13 theories about the vena cava and why it generates such</p> <p>14 large displacements and so forth, and they're a little</p> <p>15 different than what's been in the literature. So I've</p> <p>16 just checked on some of those things. I find it kind of</p> <p>17 interesting, actually.</p> <p>18 Q. Have you looked at any of the literature he's</p> <p>19 citing to as support for his assumptions to see -- to</p> <p>20 see if, A, they actually support his assumptions or, B,</p> <p>21 there may be other literature out there that</p> <p>22 contradicts?</p> <p>23 A. Well, I mean, I have looked at some of them. I</p> <p>24 haven't done a specific study like that and gone through</p> <p>25 every paper he's cited and seen whether he's done</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. Have you given him any input to the method by</p> <p>2 which he modeled the calculation?</p> <p>3 A. No.</p> <p>4 Q. So, for example, how he's -- how he's modeled</p> <p>5 the -- the strut, how he's got it affixed in that model,</p> <p>6 anything like that that you --</p> <p>7 A. Well, he's read my report, so he would -- he</p> <p>8 would -- I don't know he'd have the benefit of that</p> <p>9 information. He would know where the fatigue cracks</p> <p>10 have formed and if they were defect-associated or</p> <p>11 rim-associated, or what have you, but I don't think --</p> <p>12 beyond that, no. I mean, he's -- he's aware of the</p> <p>13 various modes of operation of these filters en vivo, and</p> <p>14 he specifically went through and looked at each of these</p> <p>15 various scenarios and tried to do an estimate of the</p> <p>16 effect of these scenarios, right? And it's -- it's --</p> <p>17 it's engineering.</p> <p>18 Q. So when it comes to his -- to a description of</p> <p>19 why the modeling was done as it was done, will you rely</p> <p>20 on Dr. McMeeking to explain that, rather than you?</p> <p>21 A. Yes, of course -- no -- what was the question?</p> <p>22 Why the modeling was done, no --</p> <p>23 Q. No, not why --</p> <p>24 A. How.</p> <p>25 Q. How the modeling was done.</p>	<p style="text-align: right;">Page 105</p> <p>1 exactly the right conclusions and whether there's</p> <p>2 alternative studies. There's always -- there's always</p> <p>3 alternative studies. But I've certainly looked at --</p> <p>4 I've found some of his notions very interesting. I</p> <p>5 mean, so I'll follow up on some of that.</p> <p>6 Q. So, again, with respect to the assumptions that</p> <p>7 he used in these calculations, you have not done</p> <p>8 anything to specifically verify them, and so you're</p> <p>9 going to let him talk about that and where they came</p> <p>10 from.</p> <p>11 A. Well, you know, I -- he's a -- as I said, I'm</p> <p>12 going to let him come up to deal with -- I teach</p> <p>13 mechanics, but to the level he does it here is something</p> <p>14 that I would defer to, if you want -- if that's the term</p> <p>15 you want. So he would defer to me on the basis of</p> <p>16 interpreting fracture surfaces.</p> <p>17 Q. So let's look for a minute at exhibit -- your</p> <p>18 Exhibit 4 for a minute. Okay, so Exhibit 4 is your</p> <p>19 supplement on Denali and Meridian.</p> <p>20 A. Yes.</p> <p>21 Q. To the MDL.</p> <p>22 A. Yes.</p> <p>23 Q. Okay. You said you had looked at McMeeking's</p> <p>24 Denali and Meridian report in the MDL as well.</p> <p>25 A. It was this one.</p>

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Page 106	<p>1 Q. Which is 8.</p> <p>2 A. I think that was --</p> <p>3 Q. Eight is his Denali and Meridian.</p> <p>4 A. But it's -- no, it's also in here.</p> <p>5 Q. Okay.</p> <p>6 A. This predates that.</p> <p>7 Q. Okay.</p> <p>8 A. So most of what I said here pertains to this.</p> <p>9 Q. Okay, so most of what you said in your -- your</p> <p>10 report which is Exhibit 4 is already contained in</p> <p>11 Exhibit 7. Okay.</p> <p>12 A. Well, I mean, that's what I'm referring to when</p> <p>13 I say I -- I was in full agreement with his conclusions.</p> <p>14 I'm referring to this -- not sure I'd even seen that by</p> <p>15 April the 1st. That's April 7th.</p> <p>16 Q. All right. So let's do it this way. When you</p> <p>17 issued your report of April the 2nd, which is Exhibit</p> <p>18 4 --</p> <p>19 A. Yes.</p> <p>20 Q. -- and said that you were in full agreement</p> <p>21 with McMeeking's analysis, findings and conclusions with</p> <p>22 respect to Denali and Meridian --</p> <p>23 A. Yes.</p> <p>24 Q. -- that was based on what he said in his report</p> <p>25 that is Exhibit 7, correct?</p>	Page 108	<p>1 the global stress situations associated with things like</p> <p>2 tilting and with migration, penetration, and his</p> <p>3 conclusions were largely that there wasn't that much</p> <p>4 difference. Now, there are these anchors that are put</p> <p>5 on the Meridian and the Denali, and these may, indeed,</p> <p>6 affect the degree of perforation to some degree, but the</p> <p>7 general conclusions that I got out of it, McMeeking's</p> <p>8 report was basically that.</p> <p>9 Q. Did -- did he use, as far as you ever</p> <p>10 understood, the same kinds of assumptions for the Denali</p> <p>11 and Meridian analysis that he used back for the G2?</p> <p>12 A. Yeah. The only difference was that the -- you</p> <p>13 know, the way that the Denali is made, you don't have</p> <p>14 these issues of wires coming out of a -- of a sheath, so</p> <p>15 -- so he -- but his effective statement was that the</p> <p>16 general design was similar. And so aside from the</p> <p>17 locality of that region and the possibility of what</p> <p>18 we've talked about, the chamfer and fretting, the</p> <p>19 general design of these things was not that different.</p> <p>20 Q. And as I asked you about the earlier models</p> <p>21 with the Meridian and the Denali, you have not done</p> <p>22 anything to verify his calculations, the mechanics of</p> <p>23 his calculations, right?</p> <p>24 A. No. I would not do that.</p> <p>25 Q. And you have not found anything that you</p>
Page 107	<p>1 A. Yes, at the time I wrote that, yes.</p> <p>2 Q. Okay. Is there anything in his -- specific to</p> <p>3 Denali and Meridian report which is Exhibit 8 --</p> <p>4 A. Yes.</p> <p>5 Q. -- that you are not in agreement with, about</p> <p>6 Meridian and Denali?</p> <p>7 A. As I sit here now, I don't know anything that I</p> <p>8 would be in disagreement with, no.</p> <p>9 Q. And so what were his basic conclusions, his</p> <p>10 general conclusions about Meridian and Denali?</p> <p>11 A. Well, I mean, the basis, as I understood it,</p> <p>12 was the fact that the -- the general design of these</p> <p>13 filters from the -- let's forget Recovery for a second,</p> <p>14 but from the G2 onwards were essentially similar. And</p> <p>15 from his perspective in calculating sort of</p> <p>16 probabilities of whether they would migrate or tilt, his</p> <p>17 general conclusions were that there wasn't much</p> <p>18 difference.</p> <p>19 The differences were somewhat cosmetic, like</p> <p>20 the addition of a hook and so forth. Some pertain to</p> <p>21 me, with respect to the chamfer and the lack -- the</p> <p>22 better situation with respect to defects after</p> <p>23 electropolishing.</p> <p>24 And these would obviously help. But what he</p> <p>25 focused on, and as I understood it in these reports, was</p>	Page 109	<p>1 thought brought question to your mind about the accuracy</p> <p>2 of his assumptions as they relate to Denali and</p> <p>3 Meridian; is that right?</p> <p>4 A. That's right.</p> <p>5 MR. DALIMONTE: Objection.</p> <p>6 Q. (By Ms. Daly) Okay, now --</p> <p>7 A. Just let me reiterate that. My assessment of</p> <p>8 the Meridian and Denali is based on what I read, right?</p> <p>9 Q. Right.</p> <p>10 A. And so I've -- I've not had the -- I don't --</p> <p>11 you don't necessarily need to see everything to be able</p> <p>12 to draw a conclusion, but I would -- I would -- I would</p> <p>13 like to see these parts before I make a definitive</p> <p>14 statement.</p> <p>15 Q. Have either you or Dr. McMeeking made an effort</p> <p>16 to see how those little anchors on the Meridian and the</p> <p>17 Denali may impact tilt, perforation or even fracture?</p> <p>18 A. Well, I can't speak for McMeeking, but</p> <p>19 certainly I have not had the benefit.</p> <p>20 Q. Okay. Do you know from any information what</p> <p>21 the trending looks like for complications in Meridian</p> <p>22 and Denali versus the earlier --</p> <p>23 A. Well, this is what I was trying to talk about</p> <p>24 earlier. The -- there are the statistics in, what was</p> <p>25 it, "Barinsky" (sic) reports? But what I've relied on</p>

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<p style="text-align: right;">Page 110</p> <p>1 is the Bard fair analysis reports, and they -- as I've 2 said before, they give a plot of the year and the 3 numbers sold, and then there's various events, 4 introduction of the Meridian and so forth, and you can 5 watch the trends. And then there's also the adverse 6 events trends as well. 7 So if you look along those, for example, and 8 you look at the number of failures, the point when the 9 Denali came in, the failures tend to drop. It goes up. 10 It trends with the actual numbers sold, but then it 11 begins to drop, and you think, "Oh, that's interesting." 12 But what is, though, these numbers are 13 cumulative numbers, and so at the point when the Denali 14 was put in, there wasn't so many. There were selling 15 those rather than a previous one, and therefore there 16 would have been less time for those things to fail. So 17 those statistics are a little biased by the fact they're 18 cumulative, but -- but -- but -- 19 Q. But you're not going to testify about the 20 relative rates of any given complication in any given 21 Bard filter, are you? 22 A. No. It's something -- I mean, I don't think I 23 would -- other people would do that better than I would; 24 it's certainly a bearing. But the point I tried to make 25 earlier was the fact that if you look at the locations</p>	<p style="text-align: right;">Page 112</p> <p>1 the -- the design of the Meridian is -- apart from these 2 anchors, is -- is essentially identical throughout the 3 whole -- G2 there's a little hook and there's, you know, 4 electropolishing and so forth. 5 But the basic form of the filter is not that 6 different, and so most of the problems that are 7 resulting from that form, as opposed to local problems, 8 you wouldn't expect there to be a vast change in the 9 performance. 10 Q. So -- so I'm clear, so even without having seen 11 an exemplar or a retrieved Eclipse, Meridian or Denali, 12 it is your opinion they are defective. 13 A. I would say on the basis of looking at their 14 design; I would say on the basis of seeing some of the 15 statistics of failures, that, yes, they're defective. I 16 would feel more secure about that if I'd actually seen 17 one and seen if they failed. 18 Q. And obviously since you haven't seen one, you 19 haven't done any of the kind of lab testing you've done 20 before on Nitinol to see what the characteristics were, 21 correct, for those filters? 22 A. Well, the fatigue -- yes, I haven't seen how 23 they -- I haven't had a direct chance to look at them. 24 Q. Nor have you done testing on the previous 25 models in that lab testing in that way on the previous</p>
<p style="text-align: right;">Page 111</p> <p>1 where these things are failing -- and I'm referring here 2 to the -- where they emerged from the sheath in that 100 3 micron zone for arms, and in the foot or in the mid-leg 4 region for the legs, those seem remarkably similar 5 throughout the whole history. 6 Q. And I'm going to talk about that in just a 7 minute with you. Did you see Dr. Fashing's report that 8 was specific to the Denali and the Meridian? 9 A. I don't think so. I've never seen that one. 10 Q. Okay, it was -- it was issued on May 11th. 11 A. No, I haven't seen that. 12 Q. Okay, and it has in it photographs and 13 examination of exemplar Meridians and Denalis; do you 14 know that? 15 A. No, I haven't seen it. The last one I saw had 16 a picture of, I think, an exemplar Eclipse. 17 Q. And with respect to the Denali and the Meridian 18 filters, since you had not seen an exemplar or a 19 retrieved Meridian and Denali, there was nothing new for 20 you to say in your role as an examiner of these filters. 21 True? 22 A. Well, in the context of what you just said, in 23 my role as examiner, I mean, I haven't had the benefit 24 of looking at them, but -- but, you know, certainly the 25 Meridian -- Denali is a little different, of course, but</p>	<p style="text-align: right;">Page 113</p> <p>1 models. 2 A. Oh, sorry, it was a different question. I 3 thought you were referring to looking at the failures. 4 I've not tested; I've not done device testing. 5 Q. Right. On any of these. 6 A. No. 7 Q. Okay. You've -- you've said a couple times 8 today that in looking at these Bard documents, which I'm 9 not precisely sure which ones you looked at, because 10 they weren't on your report reliance list so I haven't 11 refreshed myself. But at any rate, whatever you've 12 looked at, I'm going to get. 13 A. Yeah. 14 Q. You have said something like looking at the 15 Bard charts the events that you see are similar from one 16 filter model to the next. What's the similarity? 17 A. Well, what I've said is that -- there are two 18 things that come out -- there's many things that are in 19 those documents by Bard, but there's two things that I 20 focused on. One was the number of adverse events as 21 functions, the number of devices sold, and there's an 22 almost one-to-one correlation with that. 23 But what I'm was referring to was after these 24 charts -- there's a little picture of a filter, right, 25 and it has arrows saying X number failed here, Y number</p>

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<p style="text-align: right;">Page 114</p> <p>1 failed here and so forth. And with regard to fracture, 2 if you look through the series all the way from early 3 2000s up to today, these things are failing in the same 4 locations -- in general, not specific now, but they're 5 failing. The arms are failing near where the wires come 6 out of it. They do make a distinction at the sheath and 7 a little bit away from the sheath, but they're always -- 8 it's always, as we see here, more, 100 microns away. 9 And then when it comes to the feet, when it's 10 -- in the Recovery, it points to mostly in the feet, 11 which is what I see here. They have a bit more 12 statistics than I, of course. And then when it comes to 13 the G2 series, it's the feet and that mid-range. And 14 that's -- you see it virtually in every report. 15 Q. So that's what you mean by similarities -- 16 A. Yes. 17 Q. -- or model to model. Okay. 18 A. Yes. I mean, there's slight differences in 19 these, in the G2, G2-X Meridian and Express, but the 20 basic design of the filter is much the same. 21 Q. With respect to the frequency with which either 22 a foot fail -- foot fracture or an arm fracture happens, 23 starting with Recovery to Denali, you have not made that 24 analysis. 25 MR. DALIMONTE: Objection.</p>	<p style="text-align: right;">Page 116</p> <p>1 Betensky's work. 2 A. Yes. 3 Q. So let me follow up. Chamfer is one of those 4 examples that the chamfer change, in your view, may well 5 improve fracture resistance. 6 A. The chamfer change -- well, certainly would 7 help improve -- it would help alleviate one of the 8 problems, definitely. I think the one that I saw in the 9 Express, though, has not gone far enough, but it's 10 certainly better than one sharp corner. 11 Q. And then you would agree that the 12 electropolishing is another way that would improve, in 13 your mind, fracture resistance for these filters. 14 A. That undoubtedly did, and that was way too 15 late, but that undoubtedly would, yes. 16 Q. Okay. And then with respect to fracturing in 17 the foot, the change to the G2 and the slightly larger 18 wire would also assist in fracture resistance at that 19 point. 20 A. Yes, it would, certainly. 21 Q. All right. Let's talk about Bard testing of 22 filters for a moment. 23 A. Okay. 24 Q. Your information about Bard testing, does it 25 come from you reviewing the testing or McMeeking's</p>
<p style="text-align: right;">Page 115</p> <p>1 THE DEPONENT: Well, it's -- it's -- it's in 2 these reports, the Barinsky (sic) -- I can't recall 3 exactly, but, you know, there's a higher -- I can't 4 remember the details, but it was a higher percentage of 5 failures in Recovery versus a G2 and so forth. So -- 6 Q. (By Ms. Daly) Okay. But you're not -- you're 7 not going to testify about the relative frequency of 8 those, are you? 9 A. No, I mean, we would -- I mean, if, for 10 example, you cure one of the problems, like the defect 11 problem, then you might expect there to be a slightly 12 lower frequency of -- 13 Q. And that could be true if the chamfer 14 contribution -- 15 A. Exactly, but that's -- 16 Q. And that could be true with the -- 17 MR. DALIMONTE: Well, let him -- 18 THE DEPONENT: But these are rather imprecise 19 correlations from what we're talking about. So I think 20 that the statistics of people like Barinsky (sic) have 21 done where they've looked at all these failures and 22 categorized them whether they're leg, foot or migration 23 will speak for themselves, but I'm not going to rely on 24 those, no. 25 Q. (By Ms. Daly) And you're speaking now about</p>	<p style="text-align: right;">Page 117</p> <p>1 comments on the testing? 2 A. No, it's not -- I looked at them in more detail 3 in the early days, but my -- I have a general philosophy 4 on the testing. Let me just say this for a second, that 5 I work for Rolls Royce as a consultant, and they have a 6 number of extremely difficult scenarios. And to 7 understand what's going on in the testing, they generate 8 a test that reproduces the -- the problem. 9 And Bard consistently has participated in a 10 series of tests that have virtually never reproduced the 11 problem when it comes to fracture. And so the problem 12 with that is you're clearly not testing the right thing; 13 you're not doing the right thing. 14 So the details of the test are almost less 15 important, but if you've got a test where everything 16 passes and yet you put it in people's bodies and things 17 are happening -- you know, the actual implant in the 18 body is the better test, and so your lab test is 19 obviously not reflecting reality. 20 So that's been my general criticism of Bard is 21 that they've -- whether they've done tests too fast or 22 haven't put a sufficiently large deflexion of the wires, 23 those are just details, but they haven't simulated 24 what's going on. 25 Q. And have you done any work to determine how a</p>

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<p style="text-align: right;">Page 118</p> <p>1 test protocol could be done for this device that would 2 simulate those things? 3 A. Well, that's -- you know, that's something that 4 -- that -- I have not done that, but that's something 5 that Bard would need to do. I mean -- 6 Q. So just -- just -- 7 MR. DALIMONTE: Object. 8 THE DEPONENT: I mean, initially it may be that 9 they were a little bit lax, but -- but, you know, this 10 has been going on for many, many years and so they've 11 known they've had problems. And so I think some of the 12 -- maybe the money they made from selling these things 13 could have been usefully spent to try and develop a 14 better way of assessing the problem. 15 Q. (By Ms. Daly) Let me move to the next 16 question, please. So you agree that you have not tried 17 to come up with any test protocol that could be used to 18 simulate the things that you're saying Bard was unable 19 to do, or failed to do. 20 MR. DALIMONTE: Objection. 21 THE DEPONENT: Well, that's not something that 22 I would do, but -- 23 Q. (By Ms. Daly) Okay. And even if there were 24 those test protocols, would you agree with me that you 25 would have to test the protocols to see if it in fact</p>	<p style="text-align: right;">Page 120</p> <p>1 picture, as you know. So that's -- that's the issue 2 I've had. 3 Q. Yeah. And I think you've answered my question. 4 My question is simply you -- you have not yourself 5 developed any test protocol that would allow this to be 6 simulated, the complications that you're concerned about 7 to be simulated; you yourself have not done that? 8 That's my only question. 9 A. No, I wouldn't do that. 10 Q. Okay. Have you done a study of how other IVC 11 filter manufacturers have done the full measure of 12 testing? 13 A. Superficially. I mean, I haven't looked at -- 14 I've seen a little bit of what Cook's done, but that's 15 all. 16 Q. Okay. Now, you've said in the past, and today 17 too, Bard -- Bard filters' tilt may cause fracture. 18 We've talked a little about perforation. Tilting 19 leading to fracture. What is the basis for your opinion 20 that tilt may lead to fracture? 21 MR. DALIMONTE: Objection; asked and answered. 22 THE DEPONENT: Well, I mean, again, it's -- I 23 mean, the design of these devices is such that it's very 24 difficult to stop them tilting, of course. The 25 possibility of -- of leg failures, which seem to be, I</p>
<p style="text-align: right;">Page 119</p> <p>1 simulated what you were trying to simulate? 2 A. Of course. You have to develop a test which 3 reflects at least some of the reality of the failures. 4 And if you've got a test where all your parts are 5 passing, and then when they're put in, implanted in 6 someone's body and failing, then you have a problem, and 7 maybe you should be using a larger displacement or a 8 different halls duplicate or something, but I -- I saw 9 no evidence that they -- they did much of that. 10 Q. And you don't know how it would be done, 11 because you haven't tried to do it. 12 A. Well, I haven't tried to it, but there are -- I 13 mean, for example, if you were worried about, you know, 14 the displacement of the vena cava, and you've assumed a 15 certain value and all your components pass and then when 16 they get put in people's body they fail, you might think 17 that you might want to use maybe a larger displacement 18 and things like that, you know. 19 I mean, there's a lot of scenarios that one has 20 to do that -- certainly aerospace goes to extreme 21 lengths to do this, and you find the one that somehow 22 gives you a simulation of what you're trying to correct. 23 But if you're doing tests and saying, "Gee, 24 everything passed," then -- and yet the components are 25 still failing, there's something wrong with that</p>	<p style="text-align: right;">Page 121</p> <p>1 think, partly related to the design, will certainly lead 2 to tilting. 3 Tilting has the potential to -- to lead to 4 perforation because you get an unbanded situation and 5 you also have -- if there's a leg failure, then stresses 6 in the other part -- other legs would be actually 7 increased. So these things are all inter-related. And 8 I can't recall exactly, but I think some of the 9 statistics that Barinsky (sic) has looked at seem to 10 support that there's a relationship there. 11 Q. (By Ms. Daly) Have you seen any medical 12 literature, any studies, that demonstrate that tilt in 13 an IVC filter leads to perforation -- sorry, leads to 14 fracture? 15 A. No. I think we're -- we're in these same 16 situations again. It's -- it would be very difficult. 17 I've not seen that. I don't think there may -- they may 18 not even be there, because it -- you have to have it in 19 for a long time and follow it precisely and so forth. 20 Q. Following up on that, then, have you seen 21 anything that gives an estimate of probability of tilt, 22 how often a tilt would lead to fracture? 23 MR. DALIMONTE: Objection. 24 THE DEPONENT: I don't think I've seen that, 25 no.</p>

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<p style="text-align: right;">Page 122</p> <p>1 Q. (By Ms. Daly) How about any work on the</p> <p>2 quantity of your tilt necessary to lead to fracture?</p> <p>3 For example, five degrees more than fifteen degrees, do</p> <p>4 you know how any relative degree of tilt would be more</p> <p>5 likely or less likely to cause fracture?</p> <p>6 A. Well, I know that tilts of about -- above about</p> <p>7 58 80 percent, the filter becomes pretty well inactive.</p> <p>8 And the more you expose -- the more you tilt, the more</p> <p>9 you expose individual wires for the possibility of</p> <p>10 perforating. But the exact relationship between tilt</p> <p>11 and fracture is difficult to say.</p> <p>12 Q. And what do you -- what do you mean when</p> <p>13 there's a -- you said something about over 15 degrees,</p> <p>14 something about inaction?</p> <p>15 A. Well, I've -- I've -- some of the reports say</p> <p>16 once a filter gets above about -- a sufficiently large</p> <p>17 tilt, like 15 degrees, then it's basically</p> <p>18 non-functional.</p> <p>19 Q. Oh. Can you --</p> <p>20 A. I'm just -- I'm just repeating what I've read,</p> <p>21 something that I --</p> <p>22 Q. Can you think what that article is while we're</p> <p>23 sitting here?</p> <p>24 A. I think it was in -- is it the Parisian report</p> <p>25 -- there's a -- what's the name of that? There's a</p>	<p style="text-align: right;">Page 124</p> <p>1 A. You know, peripherally they have little, these</p> <p>2 little -- doesn't the Denali have a little plate --</p> <p>3 these things could all influence it. I haven't done a</p> <p>4 precise study on it.</p> <p>5 Q. Now let's talk about tilt as it relates to</p> <p>6 perforation for a moment. What do you rely on to opine</p> <p>7 that tilt can lead to perforation?</p> <p>8 A. Well, again, it's -- there's a series --</p> <p>9 McMeeking has done calculations on this and has certain</p> <p>10 theories, but my feeling on this has been that -- that</p> <p>11 there's a linkage with some -- with migration as well.</p> <p>12 Some degree of tilt means that you've got an</p> <p>13 anchor that's not anchored, and that means that the</p> <p>14 ability of the filter to move is obviously elevated</p> <p>15 because you're not fully anchored. Once the filter</p> <p>16 starts to move, the probability of perforation is</p> <p>17 likely, and all these things relate to the possibility</p> <p>18 of fracture and -- because that's what we talked about</p> <p>19 earlier with the crack growing in different directions.</p> <p>20 So I've -- I've always seen this as what I call</p> <p>21 a vicious circle. It's a synergy of events. And I</p> <p>22 think what McMeeking has been able to do is to show that</p> <p>23 some of these scenarios -- and the details are in here</p> <p>24 -- will elevate the stresses and so forth. So all this</p> <p>25 seems to be a reasonably consistent picture.</p>
<p style="text-align: right;">Page 123</p> <p>1 report that goes through the history of -- it's by a</p> <p>2 woman who used to work for the FDA.</p> <p>3 Q. Oh, Parisian?</p> <p>4 A. Parisian, that's right. There's a comment in</p> <p>5 there about that.</p> <p>6 Q. Oh. I'm just wondering -- she's an expert in</p> <p>7 the -- in the case. I'm just wondering whether you're</p> <p>8 aware of any medical study that talks about that.</p> <p>9 A. No.</p> <p>10 Q. Okay. Do you -- have you looked at all at the</p> <p>11 issue of whether electropolishing has any impact on</p> <p>12 tilt?</p> <p>13 A. No, I haven't. One could conceive that the</p> <p>14 smoother surface may have a somewhat less of a</p> <p>15 frictional resistance at the site of the vena cava, but</p> <p>16 between you and me, I don't think it would have any</p> <p>17 effect at all.</p> <p>18 Q. How about the Meridian and Denali additions of</p> <p>19 the anchors relative to tilt? Do you think that could</p> <p>20 have had an impact on improving --</p> <p>21 A. I can't remember, but they certainly would have</p> <p>22 had an impact, but I -- I don't recall the statistics of</p> <p>23 what that was.</p> <p>24 Q. Okay. And you haven't studied the mechanism by</p> <p>25 which they might or might not improve tilt.</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. So a given -- a given tilt may result in</p> <p>2 perforation, true?</p> <p>3 MR. DALIMONTE: Objection.</p> <p>4 THE DEPONENT: Of course.</p> <p>5 Q. (By Ms. Daly) Okay. But you have not been</p> <p>6 able to drill down to determine what degree of tilt, for</p> <p>7 example, would result in what perforation or where in</p> <p>8 the filter; is that fair?</p> <p>9 A. Yeah, but there's so many other variables that</p> <p>10 are involved, so it depends on -- it would be difficult</p> <p>11 to do that precisely, but no, I haven't done that.</p> <p>12 Q. And have you done any work to determine the</p> <p>13 probability of perforation in the face of any particular</p> <p>14 degree of tilt?</p> <p>15 A. I haven't done that, no.</p> <p>16 Q. Do you know if that's ever been studied in the</p> <p>17 literature?</p> <p>18 A. Not -- not to my knowledge. I mean, you've got</p> <p>19 the statistics of the failures where you could sort of</p> <p>20 piece something together. And if you looked at some of</p> <p>21 McMeeking's calculations, you might be able to say,</p> <p>22 "Well, certain scenarios would give rise to a higher</p> <p>23 stress and therefore likely to be a higher probability,"</p> <p>24 but I don't think there's any definitive studies on it.</p> <p>25 You could do a definitive study on it.</p>

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<p style="text-align: right;">Page 126</p> <p>1 Q. You don't think you could or --</p> <p>2 MR. DALIMONTE: Objection.</p> <p>3 THE DEPONENT: It would be very difficult.</p> <p>4 Q. (By Ms. Daly) Okay. Have you looked at all at</p> <p>5 the issue of tilt in non-Bard filters?</p> <p>6 A. Peripherally with the Cook filters.</p> <p>7 Q. Are you familiar with, for example, Druack's</p> <p>8 study of the Tulip and Celest filters?</p> <p>9 A. Yeah, I've looked at that. I don't recall the</p> <p>10 detail, but I've looked at that.</p> <p>11 Q. His finding was 30 percent of Tulips tilting</p> <p>12 and 48 percent of Cooks tilting. Does that --</p> <p>13 A. Yeah.</p> <p>14 Q. Do you recall that? Are you also familiar with</p> <p>15 the Zhou, Z-h-o-u study of Cook Celest showing a 73</p> <p>16 percent tilt, 73 percent of filters tilting --</p> <p>17 A. Yeah, I did a Cook report some time ago and I</p> <p>18 remember those things. I haven't looked recently.</p> <p>19 Q. All right. Let's talk just a little more about</p> <p>20 perforation. We've talked a good bit about that. Have</p> <p>21 you looked at medical literature about the</p> <p>22 susceptibility or lack thereof of perforation in Bard</p> <p>23 filters?</p> <p>24 A. I -- I've seen papers, yes, that talk about</p> <p>25 that, yes.</p>	<p style="text-align: right;">Page 128</p> <p>1 THE DEPONENT: Well, you see, this is where law</p> <p>2 and engineering have a problem. The -- the fatigue life</p> <p>3 is something like a function of the tenth power of the</p> <p>4 stress, so it takes a little teeny bit of stress to get</p> <p>5 a huge change in life. So all I'm saying is that when</p> <p>6 you see a big number, it means that the probability of</p> <p>7 that happening is more likely than if it was a small</p> <p>8 number, right? I'm not -- I'm not saying McMeeking's</p> <p>9 calculations say they all should fail in fifteen cycles;</p> <p>10 life's certainly not like that. You can't say you're</p> <p>11 going to die after 30 years; you might die after 50 or</p> <p>12 60, that kind of thing.</p> <p>13 But I think what I find compelling of that is I</p> <p>14 think in numbers of whether they're small or large,</p> <p>15 basically, not the absolute values, and I think some of</p> <p>16 these -- these calculations that show, for example, a</p> <p>17 perforation could cause a pretty large elevation of</p> <p>18 stress or break or strain are very compelling.</p> <p>19 Q. And I guess that was really my point, was</p> <p>20 whether anything that you've taken from McMeeking allows</p> <p>21 you to give any opinion on the probability of a</p> <p>22 complication happening over some set period of time.</p> <p>23 A. That's a good question. It's very difficult to</p> <p>24 answer. There's too many -- too many other variables,</p> <p>25 so you can't -- you really can't, "It's high, low or</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. Do you remember what papers?</p> <p>2 A. Not offhand, but, I mean, I -- I -- I mean, I</p> <p>3 remember the original Hull and Robinson papers. There's</p> <p>4 been -- some are referenced in here.</p> <p>5 Q. And the Hull one, that was a -- you remember</p> <p>6 that was a small study of --</p> <p>7 A. Yeah, small study.</p> <p>8 Q. -- 14. Okay.</p> <p>9 A. But, you know, with these things -- well, I'm</p> <p>10 was going to say, you talk about reliance on McMeeking,</p> <p>11 that some of the calculations that he does show</p> <p>12 alarmingly large increases in strain associated with</p> <p>13 perforations. And if you compare those numbers with the</p> <p>14 fatigue limits, then it would suggest rather short</p> <p>15 fatigue lives, right?</p> <p>16 So, again, I'm not saying that those numbers</p> <p>17 you can rely on precisely, but the magnitude of those</p> <p>18 effects is sufficiently large that it's consistent with</p> <p>19 what you've called my hypothesis.</p> <p>20 Q. Well, let's talk about that short fatigue life</p> <p>21 you talk about from McMeeking's work, okay? Based on</p> <p>22 your review of his work, is it your conclusion that</p> <p>23 those strains that he's calculated will lead to quick</p> <p>24 fatigue of parts of the filter?</p> <p>25 MR. DALIMONTE: Objection.</p>	<p style="text-align: right;">Page 129</p> <p>1 medium," but it's -- you couldn't -- it's very difficult</p> <p>2 to put a number on. Maybe a statistician could. I</p> <p>3 couldn't do that. There's too many other variables.</p> <p>4 Q. And, again, this takes us back to what we were</p> <p>5 talking about before. It's not just a matter of this</p> <p>6 one's tilting and we're going to calculate out a</p> <p>7 probability of fracture; it could be tilting a certain</p> <p>8 degree --</p> <p>9 A. Yeah, exactly, yeah.</p> <p>10 Q. It could be tilting with perforation; it could</p> <p>11 be tilting without perforation. Many variables.</p> <p>12 A. Yeah, but you can at least get some trends.</p> <p>13 You can say that if it tilts, something happens; if it</p> <p>14 migrates, something happens, and these numbers are then</p> <p>15 consistent with the overall picture of the more complex</p> <p>16 state.</p> <p>17 Q. And are you -- are you familiar with the</p> <p>18 studies of, for example, Cook filters and perforation</p> <p>19 percentages in those filters?</p> <p>20 A. I have looked. I don't recall, but I've looked</p> <p>21 at them, yeah.</p> <p>22 Q. Do you recall in Zhou -- again, it's the Zhou</p> <p>23 that's spelled Z-h-o-u --</p> <p>24 A. Yeah.</p> <p>25 Q. That he reported a 90 -- I'm sorry, he reported</p>

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<p style="text-align: right;">Page 130</p> <p>1 an 86 percent perforation rate in Cook Select?</p> <p>2 A. Yeah, I seem to recall --</p> <p>3 Q. It was high?</p> <p>4 A. It was high, yes.</p> <p>5 Q. And Durack studied the Tulip and reported a 93</p> <p>6 percent perforation; is that right?</p> <p>7 A. Yeah.</p> <p>8 Q. Okay. We talked earlier about your definition</p> <p>9 of "prone" and "susceptibility" that you've stated in</p> <p>10 your reports.</p> <p>11 A. Yes.</p> <p>12 Q. I'm moving to something else. In your report</p> <p>13 of April 1, 2017 -- let me find it.</p> <p>14 A. No. 4, right? This one?</p> <p>15 MR. DALIMONTE: What report were you referring</p> <p>16 to? His original?</p> <p>17 MS. DALY: No, April.</p> <p>18 THE DEPONENT: Supplementary report, Meridian</p> <p>19 and Denali.</p> <p>20 MS. DALY: I've got to go in search of it.</p> <p>21 THE DEPONENT: Oh, there's another one here.</p> <p>22 There's two of them.</p> <p>23 Q. (By Ms. Daly) Yeah. The one I wanted was the</p> <p>24 rebuttal, Rebuttal to Defendant's Expert Opinions.</p> <p>25 A. Okay. I've got it. That's No. 3.</p>	<p style="text-align: right;">Page 132</p> <p>1 fractures. I can't remember the numbers now, but in the</p> <p>2 studies I've looked at they've been pretty severe. And</p> <p>3 I think it's incumbent upon a medical device company to</p> <p>4 design something which does not have such a large</p> <p>5 failure rate. I'm using the term loosely, but I think</p> <p>6 it's certainly -- if we were going to have one of those</p> <p>7 things put in and we saw the failure rates, to me, that</p> <p>8 would be an unacceptable failure rate.</p> <p>9 Q. Okay. So who is it unacceptably high to? Are</p> <p>10 you saying from your perspective?</p> <p>11 A. Of course, from my perspective, but I think</p> <p>12 anybody's perspective who looked at those numbers.</p> <p>13 Q. Has the FDA said it's an unacceptably high</p> <p>14 rate?</p> <p>15 MR. DALIMONTE: Objection.</p> <p>16 THE DEPONENT: I don't know.</p> <p>17 Q. (By Ms. Daly) How about the Society of</p> <p>18 Interventional Radiologists? Have they made any such</p> <p>19 statements?</p> <p>20 MR. DALIMONTE: Objection.</p> <p>21 THE DEPONENT: I don't know.</p> <p>22 Q. (By Ms. Daly) Are you aware of any</p> <p>23 organization that's concluded that Bard filters have an</p> <p>24 unacceptably high incidence of any kind of complication?</p> <p>25 A. Any organization?</p>
<p style="text-align: right;">Page 131</p> <p>1 Q. All right. In that report, let's look at Page</p> <p>2 5, and at the beginning of paragraph -- third full</p> <p>3 paragraph that begins "In conclusion,"</p> <p>4 A. Uh-huh.</p> <p>5 Q. Okay. Hold on one second. Okay. It says:</p> <p>6 "In conclusion, Dr. Fashing appears to</p> <p>7 be pointing to individual factors that</p> <p>8 contributed to" --</p> <p>9 This is the quote I'm going to ask you about:</p> <p>10 "...the totally unacceptable fatigue</p> <p>11 failure rate of the Bard IVC filters."</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. All right. Then several lines down, seven</p> <p>15 lines down, you say:</p> <p>16 "Bard filters displayed an</p> <p>17 unacceptably high incidence of filter</p> <p>18 fractures."</p> <p>19 A. Uh-huh.</p> <p>20 Q. That's what I want to ask you about.</p> <p>21 A. Uh-huh.</p> <p>22 Q. What is -- what do you mean when you use the</p> <p>23 term, "unacceptably high," in this context?</p> <p>24 A. It's -- it's -- I mean, we're talking about a</p> <p>25 device which has suffered a high percentage of</p>	<p style="text-align: right;">Page 133</p> <p>1 Q. Yeah.</p> <p>2 A. Offhand I can't say.</p> <p>3 Q. When you used the term "unacceptably high</p> <p>4 incidence," were you speaking of as to fracture or any</p> <p>5 other type of complication for the Bard filters?</p> <p>6 A. Well, I use the term "unacceptable fatigue</p> <p>7 failure rate," so I'm referring specifically there to</p> <p>8 the -- I mean, components that are put in the body</p> <p>9 should not fatigue, because that's -- that's a very</p> <p>10 severe problem. And the -- the numbers -- the</p> <p>11 statistics of these, these fractures are particularly</p> <p>12 high. So in my terminology they're unacceptable.</p> <p>13 It would be hard for me to believe that</p> <p>14 organizations have not made a comment about it, but I</p> <p>15 haven't read all the FDA stuff, so I can't comment on</p> <p>16 that, but it certainly would be a surprise to me if they</p> <p>17 didn't.</p> <p>18 Q. Do you hold the opinion that there's any other</p> <p>19 complication in the Bard filter that is at the</p> <p>20 unacceptably high rate, in your opinion?</p> <p>21 A. Well, again, it's a -- it's a personal</p> <p>22 statement, but I think since -- since the fractures are</p> <p>23 all related to perforations, can be related to</p> <p>24 perforations and tilts and so forth, these filters were</p> <p>25 functioning in a situation that led to adverse events.</p>

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<p style="text-align: right;">Page 134</p> <p>1 These are documented in more data and so forth, so --</p> <p>2 but I don't know who's -- whether the Society of</p> <p>3 Interventional Cardiologists have actually made comments</p> <p>4 on those; I've not read those, but I'd be surprised if</p> <p>5 they didn't.</p> <p>6 Q. How are you -- how are you coming up with a</p> <p>7 determination of what the incidence of these various</p> <p>8 complications are in Bard in order for you to say</p> <p>9 they're unacceptably high?</p> <p>10 A. Well, I've -- I mean, there's a whole set of</p> <p>11 data bases. I've looked at certain papers which have</p> <p>12 done smaller studies with numbers -- like 40 percent</p> <p>13 failures have been seen. That's obviously a small</p> <p>14 study. There's more data that has -- there's -- what do</p> <p>15 they call it -- Labinski (sic) report or something?</p> <p>16 Q. Betensky.</p> <p>17 A. Betensky report -- that lists some of these</p> <p>18 things. These -- these -- these seem extremely high to</p> <p>19 me, and my understanding of general engineering, these</p> <p>20 are unacceptably high.</p> <p>21 Q. What is the -- what is the study that you're</p> <p>22 talking about that's 40 percent rate of what?</p> <p>23 A. Oh, there was -- some of the -- I remember</p> <p>24 having an interchange with Richard North about this,</p> <p>25 that some of the earlier studies that I list in here --</p>	<p style="text-align: right;">Page 136</p> <p>1 Q. Okay. Which ones are you thinking of?</p> <p>2 A. Well, there was -- there was one fracture, of</p> <p>3 course, and there was a number of -- I think it was</p> <p>4 instances of tilt and a little -- and migrations. This</p> <p>5 was all very early. And if you took -- what did he do?</p> <p>6 He looked at 27 patients or something. You looked at</p> <p>7 the number of those, that was a -- and they were -- the</p> <p>8 filters were implanted for a relatively short period of</p> <p>9 time. The rate of adverse events was far in excess of</p> <p>10 what the history of the Simon filter had been, so --</p> <p>11 Q. How do you know that?</p> <p>12 A. Because that's what I've read.</p> <p>13 Q. How do you know what the experience of the</p> <p>14 Simon Nitinol filter was up to the time that Ash did</p> <p>15 that study and how it -- how it would compare?</p> <p>16 A. Well, I -- I think that's -- I read that in</p> <p>17 some of the reports. I think that was in this Parisian</p> <p>18 report as well.</p> <p>19 Q. Okay. So in the Ash study there was one</p> <p>20 asymptomatic migration. Do you recall that?</p> <p>21 A. Yeah, something like that.</p> <p>22 Q. How many migrations were there in Simon Nitinol</p> <p>23 filters?</p> <p>24 A. Offhand, I can't remember, but -- but we're</p> <p>25 looking -- and what we're not -- what we're not</p>
<p style="text-align: right;">Page 135</p> <p>1 I think they're cited in here, where they looked and</p> <p>2 they saw a large number of failures. Nicholson or</p> <p>3 something like that was one, I think. There's a number</p> <p>4 of them and they're, of course, small studies, so they</p> <p>5 don't -- they don't portray the overall statistics which</p> <p>6 come out of --</p> <p>7 Q. And they may -- they may over-state them for</p> <p>8 some reason.</p> <p>9 A. Of course, yeah, because it's a small study.</p> <p>10 Q. So --</p> <p>11 A. But if you've got a device -- I mean, if you</p> <p>12 just compare the Simon filter with the Ash -- study that</p> <p>13 Ash did. Ash had a very small duration of filters being</p> <p>14 implanted and got -- got several adverse events in that</p> <p>15 study, which in -- percentage-wise was far greater of</p> <p>16 the whole history like the Simon. So -- so there's --</p> <p>17 there's a lot of evidence here that this was not an</p> <p>18 acceptable --</p> <p>19 Q. Okay.</p> <p>20 MR. DALIMONTE: Let him finish.</p> <p>21 THE DEPONENT: -- place.</p> <p>22 Q. (By Ms. Daly) Okay, so let's talk about Ash.</p> <p>23 You just put a whole lot out there. You just said that</p> <p>24 the Ash study had a number of reported complications.</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 137</p> <p>1 comparing is not numbers but rates. There was a very</p> <p>2 small study where filters were in for a short period of</p> <p>3 time, and we're comparing with a somewhat larger study</p> <p>4 of the past. And so all I'm saying is that there were</p> <p>5 indications immediately that there were -- that there</p> <p>6 was -- there was situations that could have been looked</p> <p>7 at.</p> <p>8 Q. There were also a number of studies -- I</p> <p>9 noticed you didn't cite any of them -- that had zero</p> <p>10 complication issues for Bard filters in those studies.</p> <p>11 MR. DALIMONTE: Objection.</p> <p>12 Q. (By Ms. Daly) So my point is -- my point is</p> <p>13 you didn't make a -- an exhaustive review of all studies</p> <p>14 of Bard filters to see what each one of them determined.</p> <p>15 Fair --</p> <p>16 MR. DALIMONTE: Objection.</p> <p>17 Q. (By Ms. Daly) -- to say?</p> <p>18 A. No, but, I mean, there has been studies on the</p> <p>19 statistics of adverse events in these devices, and I've</p> <p>20 certainly read about those, and it would be very hard to</p> <p>21 argue that the failure rate, particularly due to</p> <p>22 fracture of a Bard filter, was acceptable.</p> <p>23 Q. What study is there that has done a statistical</p> <p>24 review of fracture in a Bard filter?</p> <p>25 A. Well, there's -- there's the statistics of --</p>

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<p style="text-align: right;">Page 138</p> <p>1 of -- I mean, there's -- there's the MAUDE data that has</p> <p>2 the adverse events, right? There's a number of --</p> <p>3 those statistics can be somewhat flawed, but they list</p> <p>4 the number of filters that have failed in a certain way,</p> <p>5 and there's the Barinsky (sic) report which has the</p> <p>6 statistics of different failure rates, so -- and I can't</p> <p>7 remember exactly the numbers of what those rates are</p> <p>8 offhand, but -- but --</p> <p>9 Q. You have not done a review to come up with a</p> <p>10 statistical analysis of rates of any complication with a</p> <p>11 Bard filter, fair?</p> <p>12 A. I'm just looking at -- I'm just reading people</p> <p>13 who have done those things.</p> <p>14 Q. And really, Betensky, I think you're aware of</p> <p>15 Betensky is the expert for plaintiffs in this case who</p> <p>16 is a statistician; you know that?</p> <p>17 A. Yes, of course.</p> <p>18 Q. Okay. Would you defer to her on her analysis</p> <p>19 of what the statistics show?</p> <p>20 A. Well, she probably knows more about statistics</p> <p>21 than I do.</p> <p>22 Q. So you would defer to her?</p> <p>23 A. I guess I would, yes.</p> <p>24 Q. Okay. We have talked about this before, and I</p> <p>25 want to be sure that I am absolutely clear on what it is</p>	<p style="text-align: right;">Page 140</p> <p>1 that just a drop-in from her report, as opposed to --</p> <p>2 what I mean is, as opposed to your having done some</p> <p>3 analysis of her analysis?</p> <p>4 A. Oh, no, no. Yes, I mean, it's almost</p> <p>5 background that it's -- that I used that, because it was</p> <p>6 a -- it indicates that there are specific functions of</p> <p>7 these filters which are, dare I say it, characteristic.</p> <p>8 And so she had the data for that, so that's why I put it</p> <p>9 in.</p> <p>10 Q. Have you ever discussed her analysis with her?</p> <p>11 A. No.</p> <p>12 Q. Have you read the Excel spreadsheets or</p> <p>13 reviewed the Excel spreadsheets that she created as part</p> <p>14 of that report?</p> <p>15 A. I don't think I've gone in any detail, no.</p> <p>16 Q. So I take it you have not undertaken to verify</p> <p>17 what her analysis was.</p> <p>18 A. No.</p> <p>19 MR. DALIMONTE: Objection.</p> <p>20 Q. (By Ms. Daly) Was that a "no"?</p> <p>21 A. "No."</p> <p>22 Q. Did you provide her any information?</p> <p>23 A. No, I did not.</p> <p>24 Q. Okay. And I take it you didn't write any part</p> <p>25 of her report.</p>
<p style="text-align: right;">Page 139</p> <p>1 you're saying on this one point in this litigation.</p> <p>2 Is it your opinion that it is more likely than</p> <p>3 not that any given Bard filter that is in situ will</p> <p>4 fracture?</p> <p>5 MR. DALIMONTE: Objection.</p> <p>6 THE DEPONENT: I can't say that.</p> <p>7 Q. (By Ms. Daly) Okay. Same question with any</p> <p>8 Bard filter in situ; more likely than not that it will</p> <p>9 perforate or tilt or migrate?</p> <p>10 MR. DALIMONTE: Objection.</p> <p>11 THE DEPONENT: Well, I mean, the more likely</p> <p>12 than not means you -- you're talking greater than 51</p> <p>13 percent, so --</p> <p>14 Q. (By Ms. Daly) Greater than 50 percent.</p> <p>15 A. Well, you can't say that.</p> <p>16 Q. Let's talk a minute about Betensky, if we</p> <p>17 could. You did not really discuss her analysis in your</p> <p>18 report; you -- you</p> <p>19 A. No, I don't.</p> <p>20 Q. Yeah, in Exhibit 2 you comment on her report at</p> <p>21 Page 4.</p> <p>22 A. Mainly because I was -- my focus has been on</p> <p>23 identifying the fracture and trying to understand what</p> <p>24 -- what's causing these fractures, and so --</p> <p>25 Q. So what you put in your report at Page 4, was</p>	<p style="text-align: right;">Page 141</p> <p>1 A. No.</p> <p>2 Q. Have you read the report of Bard</p> <p>3 biostatistician -- his name is Ronald Thisted?</p> <p>4 A. Don't believe so.</p> <p>5 Q. Have you ever heard of him?</p> <p>6 A. No.</p> <p>7 Q. University of Chicago?</p> <p>8 A. Never heard of him.</p> <p>9 Q. Okay. Do you know with any specificity the</p> <p>10 methodology by which Dr. Betensky -- which Dr. Betensky</p> <p>11 employed to reach her conclusions?</p> <p>12 A. Yeah, I mean, I have a footnote here which -- I</p> <p>13 mean, I was more interested in just getting a general</p> <p>14 feeling for the -- the -- what problems this particular</p> <p>15 filter had, or filters had, and how they -- so, I mean,</p> <p>16 she has this risk ratio which seemed like -- I mean, I</p> <p>17 didn't go into great detail, but it indicates whether</p> <p>18 something is more likely than not. So that's what I was</p> <p>19 -- I didn't go into any great detail.</p> <p>20 I mean, just for example, it says here the</p> <p>21 Eclipse has a particularly low number, but that's</p> <p>22 because there wasn't so many Eclipses put in. So,</p> <p>23 again, statistics are a little bit tilted by that,</p> <p>24 but --</p> <p>25 Q. Did --</p>

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<p style="text-align: right;">Page 142</p> <p>1 MR. DALIMONTE: Let him finish.</p> <p>2 Q. (By Ms. Daly) Go ahead.</p> <p>3 A. I mean, really I'm just giving a bit of</p> <p>4 background there that indicates what's --</p> <p>5 Q. I noticed it was in the introduction.</p> <p>6 A. Yeah.</p> <p>7 Q. So did you understand that her analysis was</p> <p>8 comparing the Bard filters after Simon Nitinol to the</p> <p>9 Simon Nitinol?</p> <p>10 A. As I understood it, yes.</p> <p>11 Q. Rather than against some other filter on the</p> <p>12 market.</p> <p>13 A. Yes.</p> <p>14 Q. And did you notice that she, between her --</p> <p>15 well, have you seen her second report? She had an MDL</p> <p>16 report and then a rebuttal report. Have you seen that?</p> <p>17 A. I've not seen the rebuttal.</p> <p>18 Q. Okay. Do you know that she speaks of risk</p> <p>19 ratios and then reporting risk ratios?</p> <p>20 A. I don't recall that, actually.</p> <p>21 Q. Do you know the difference between those?</p> <p>22 A. Well, I can guess what it is.</p> <p>23 Q. From a biostatistician's standpoint, do you</p> <p>24 know?</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 144</p> <p>1 2. We're off the record at 1:58 p.m.</p> <p>2 (Recess)</p> <p>3 VIDEOGRAPHER: We're back on the record. This</p> <p>4 marks the beginning of Disk No. 3 in the deposition of</p> <p>5 Robert O. Ritchie, Ph.D. The time is 2:09 p.m.</p> <p>6 Q. (By Ms. Daly) Dr. Ritchie, would you glance at</p> <p>7 the CV that is with your Report No. 2?</p> <p>8 A. The CV?</p> <p>9 Q. Your CV should have been in there.</p> <p>10 A. Yes, it is. Should be.</p> <p>11 Q. Is it? Unless I cut it off and didn't do it.</p> <p>12 A. Yes, there it is.</p> <p>13 Q. Can you just glance at that and tell me if that</p> <p>14 is your up-to-date one? This is done so recently, I</p> <p>15 assume it was, but if there's anything that is missing.</p> <p>16 A. Well, the only thing, it's probably irrelevant,</p> <p>17 but I was made a Fellow of the Royal Society this month.</p> <p>18 Q. Oh, congratulations.</p> <p>19 A. I was -- signed the book signed by Newton. But</p> <p>20 that's the only thing.</p> <p>21 Q. Okay. So let's talk about your bills for a</p> <p>22 minute. Let's make this Exhibit 10.</p> <p>23 (Whereupon, Exhibit No. 10 was marked for</p> <p>24 identification.)</p> <p>25 Q. You handed me this this morning. Let me just</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. Okay. Are you of the opinion that the Simon</p> <p>2 Nitinol filter is an alternative, safer product than any</p> <p>3 of the later Bard filters?</p> <p>4 A. Well, again, that speaks to -- I mean, what do</p> <p>5 you mean by "safer"? I mean, it was -- as I understand</p> <p>6 it, it was less likely to migrate. It had a -- it was</p> <p>7 -- it was not -- it was a permanent filter, as I</p> <p>8 understand it. So I -- I just -- I think that in terms</p> <p>9 of its rates of adverse events, they were less than --</p> <p>10 than -- than the Recovery, and maybe the subsequent G2s,</p> <p>11 but the safety with regard to medical, I don't know. I</p> <p>12 mean, it's -- it's -- it's -- with this little bit at</p> <p>13 the top which is pushed against the vena cava, it seemed</p> <p>14 in principle to be less likely to migrate and so forth</p> <p>15 and I think the statistics support that.</p> <p>16 Q. And do you understand that, insofar as it being</p> <p>17 an alternative product for the later generations of</p> <p>18 Bard, it was solely a permanent filter; it couldn't --</p> <p>19 A. Exactly, exactly. I mean, the whole basis of</p> <p>20 the Recovery, it was -- where the name comes from.</p> <p>21 Q. Okay.</p> <p>22 A. Could we, per chance, take a -</p> <p>23 Q. That would be helpful, because I can get myself</p> <p>24 organized to work on wrapping up.</p> <p>25 VIDEOGRAPHER: This marks the end of Disk No.</p>	<p style="text-align: right;">Page 145</p> <p>1 hand you that and ask you to tell us what work that</p> <p>2 covers.</p> <p>3 A. Well, the first one was just the meeting last</p> <p>4 year on -- with all the lawyers about these cases.</p> <p>5 That's --</p> <p>6 Q. Oh, I should have marked that. So that was</p> <p>7 March 11th, 2006 --</p> <p>8 MR. DALIMONTE: Hold on.</p> <p>9 MS. DALY: You better look at that.</p> <p>10 THE DEPONENT: And that's one's -- that's the</p> <p>11 bill for this.</p> <p>12 MR. DALIMONTE: Right. Yep. Okay.</p> <p>13 MS. DALY: So let me just make the second page</p> <p>14 11.</p> <p>15 (Whereupon, Exhibit 11 was</p> <p>16 marked for identification.)</p> <p>17 MR. DALIMONTE: I would like to note on the</p> <p>18 record, however, we should -- well, never mind.</p> <p>19 Q. (By Ms. Daly) Okay. So let me ask you this,</p> <p>20 to get it clear. Eleven is work done in March of '16.</p> <p>21 Was that on any particular report or was that just</p> <p>22 general work with the plaintiff's attorneys?</p> <p>23 A. No, no, that was -- actually that's a rebill.</p> <p>24 I think the event was -- these are the only two bills</p> <p>25 I've had since there's been consolidated cases dealt</p>

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Page 146	<p>1 with.</p> <p>2 Q. Okay.</p> <p>3 A. And this was just a general meeting, and that's</p> <p>4 specific to this report.</p> <p>5 Q. Okay. So then Exhibit 10 is specific to your</p> <p>6 MDL reports?</p> <p>7 A. Yes -- no. Report...I haven't billed the</p> <p>8 recent one.</p> <p>9 Q. Okay. Can you estimate how much time you have</p> <p>10 spent since the time that is on this bill dated March</p> <p>11 17th, 2017?</p> <p>12 A. Now, does that include the individual --</p> <p>13 MR. DALIMONTE: The Bellweather cases?</p> <p>14 THE DEPONENT: Yes.</p> <p>15 MR. DALIMONTE: We'll treat those separately.</p> <p>16 We'll take them up in the Bellweather.</p> <p>17 THE DEPONENT: So it's a few hours.</p> <p>18 Q. (By Ms. Daly) Okay. Are -- are you able to</p> <p>19 put together your time you spent on the Bellweather so</p> <p>20 we'll have that when you and I --</p> <p>21 A. I hope -- yeah.</p> <p>22 MR. DALIMONTE: Or we can always get that to</p> <p>23 you.</p> <p>24 THE DEPONENT: I haven't billed any of that</p> <p>25 yet. I don't know when the next deposition will be, but</p>	Page 148
Page 147	<p>1 A. Yes.</p> <p>2 Q. Okay, and what was your understanding of that</p> <p>3 question?</p> <p>4 A. Well, to me the operative words were for a</p> <p>5 "particular filter" could you say that it would be more</p> <p>6 likely to fracture than not. And --</p> <p>7 Q. Well, let me ask you this question. Can you</p> <p>8 say, to a reasonable degree of engineering and</p> <p>9 scientific certainty, that all of the imperfections in</p> <p>10 the draw markings that you describe and the dentation,</p> <p>11 the centerless grinding markings, increase the</p> <p>12 likelihood of the filter fracturing?</p> <p>13 A. That's undeniable.</p> <p>14 Q. And can you say, to a reasonable degree of</p> <p>15 scientific and engineering certainty, that the edge of</p> <p>16 the chamfer increases the stress and strain and</p> <p>17 increases the risk of the filter fracturing at that</p> <p>18 location?</p> <p>19 A. It increases the stress and strain in that</p> <p>20 local scenario, and therefore since that's a potential</p> <p>21 place of fracture, then it increases the probability</p> <p>22 there could be a fracture there.</p> <p>23 Q. And you're not testifying or trying to tell the</p> <p>24 jury that the arm is going to break there 51 percent of</p> <p>25 the time.</p>	Page 149
Page 147	<p>1 presumably I'll have billed it.</p> <p>2 Q. (By Ms. Daly) Okay. I think we said this this</p> <p>3 morning, but you have submitted a case-specific report</p> <p>4 on each of the five cases; is that right?</p> <p>5 A. Yes.</p> <p>6 Q. Okay, all right.</p> <p>7 A. They're in, heads or tails.</p> <p>8 Q. All right, and I will look at those, and we</p> <p>9 will reconvene.</p> <p>10 MR. DALIMONTE: All right, why don't we take a</p> <p>11 break?</p> <p>12 VIDEOGRAPHER: Going off the record, the time</p> <p>13 is 2:13 p.m.</p> <p>14 (Recess)</p> <p>15 VIDEOGRAPHER: We are back on the record. The</p> <p>16 time is 2:30 p.m.</p> <p>17 CROSS-EXAMINATION BY</p> <p>18 MR. DALIMONTE: Q. Good afternoon,</p> <p>19 Dr. Ritchie, Dalimonte on behalf of the plaintiffs.</p> <p>20 A. Yes.</p> <p>21 Q. Just for clarification, you were asked a couple</p> <p>22 of questions by Taylor Daly concerning whether or not</p> <p>23 you could say more likely than not that the filters --</p> <p>24 any particular filter would fracture 51 percent of the</p> <p>25 time. Do you remember being asked that question?</p>	Page 149
	<p>1 A. No, that's whole -- that's why I answered the</p> <p>2 question the way I did. For a particular filter, if you</p> <p>3 had -- if you said it had a 51 percent of fracture, then</p> <p>4 you'd expect to see 51 percent of those filters</p> <p>5 fracturing. It's just the probability of a fracture,</p> <p>6 the likelihood of a fracture is increased by these</p> <p>7 details.</p> <p>8 Q. Okay, and also the same would be true with</p> <p>9 perforation -- let me ask the question on that subject.</p> <p>10 Can you say, to a reasonable degree of scientific and</p> <p>11 engineering certainty, that the perforation will</p> <p>12 increase the likelihood of fracture?</p> <p>13 A. That is my understanding.</p> <p>14 Q. Okay. Similarly, can you say, to a reasonable</p> <p>15 degree of scientific engineering certainty, that tilt</p> <p>16 will increase the likelihood of perforation and/or</p> <p>17 fracture, or both?</p> <p>18 A. That's my understanding as well.</p> <p>19 Q. Okay. And that's because when it's in the tilt</p> <p>20 position, as you described earlier, the stresses and</p> <p>21 strains are no longer equally distributed amongst the</p> <p>22 filter.</p> <p>23 A. That's one of the reasons, yes.</p> <p>24 Q. And, for instance, in the chamfer situation</p> <p>25 you've described that there would be been an increase of</p>	

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<p style="text-align: right;">Page 150</p> <p>1 stress and strain at that particular location as the</p> <p>2 vessel, the dynamics of the vessel move.</p> <p>3 A. Yes. I mean, the contact of a wire against a</p> <p>4 sharp corner can lead to very high stress concentration.</p> <p>5 Q. And the same thing with a hook or the foot, the</p> <p>6 anchoring foot -- and I'm talking across the board --</p> <p>7 A. Yes.</p> <p>8 Q. For all iterations of the Bard IVC filter line.</p> <p>9 A. Yes.</p> <p>10 Q. With the exception of the Simon Nitinol.</p> <p>11 A. Yes. I mean, these -- these details can</p> <p>12 increase the likelihood of fracture. It doesn't mean to</p> <p>13 say that a particular filter will fracture that way, and</p> <p>14 if it doesn't fracture that way that that particular</p> <p>15 detail is unimportant, but they all synergistically work</p> <p>16 to promote fracture. And if there is any stress</p> <p>17 concentration -- any stress concentration will likely</p> <p>18 increase the probability of fracture. It doesn't mean</p> <p>19 to say they will fracture, then, necessarily, in a given</p> <p>20 case.</p> <p>21 Q. But it certainly increase -- increases the</p> <p>22 fracture of the filter --</p> <p>23 A. Potentially. The operative words are for a</p> <p>24 "particular filter," that's the case.</p> <p>25 Q. And that's what you were asked by --</p>	<p style="text-align: right;">Page 152</p> <p>1 scientific and engineering certainty, that those</p> <p>2 markings would increase the likelihood of the filter</p> <p>3 fracturing at that area that you described, the hook,</p> <p>4 where the centerless markings are?</p> <p>5 A. Absolutely.</p> <p>6 Q. Okay. And the basis for those opinions are set</p> <p>7 forth in your reports that you've submitted already,</p> <p>8 correct?</p> <p>9 A. Absolutely.</p> <p>10 Q. All right.</p> <p>11 Oh. Your discipline is in material science,</p> <p>12 correct?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. You were asked a number of questions</p> <p>15 that were, like, biostats and medical choices. That's</p> <p>16 not your particular discipline, is it?</p> <p>17 A. No. I mean, as a -- I mean, I've been around</p> <p>18 the block a few years in the science community, so I can</p> <p>19 appreciate some of these things, but, no, I'm not a</p> <p>20 biostatistician. I'm not a medical doctor or anything</p> <p>21 like that, so...</p> <p>22 Q. You were also asked a question by Ms. Daly</p> <p>23 about whether there was an exact relationship of tilt</p> <p>24 and fracture, and I think your response was "That's</p> <p>25 impossible to say." Can you explain what you meant?</p>
<p style="text-align: right;">Page 151</p> <p>1 A. Yes, I understand it being beyond a reasonable</p> <p>2 -- you know, what was the words you used --</p> <p>3 Q. Well --</p> <p>4 A. The engineering certainty or whatever you call</p> <p>5 it, it's saying that there's more than a 50 percent</p> <p>6 chance something will happen. For a given filter you</p> <p>7 can't say that there's a 50 percent chance that a given</p> <p>8 filter will fracture.</p> <p>9 Q. But what you can say is that more than 51</p> <p>10 percent, or even higher, closer to 90 percent or 95</p> <p>11 percent of the time, or 95 percent confidence level --</p> <p>12 A. Yeah.</p> <p>13 Q. -- that the likelihood of a fracture is</p> <p>14 increased, that with the perforation or tilt or at the</p> <p>15 chamfer, or the imperfections on the wire itself all</p> <p>16 contribute to fracturing?</p> <p>17 THE DEPONENT: That is --</p> <p>18 MS. DALY: Object to the form.</p> <p>19 THE DEPONENT: That's how I understand it.</p> <p>20 It's undeniable to me.</p> <p>21 Q. (By Mr. Dalimonte) I just want to make sure I</p> <p>22 have this on the record; I may have already asked this</p> <p>23 question. The centerless markings on the hook --</p> <p>24 A. Yes.</p> <p>25 Q. Can you say, to a reasonable degree of</p>	<p style="text-align: right;">Page 153</p> <p>1 A. Well, I mean, the point is that the two events</p> <p>2 are coupled. If you get a tilt, you don't necessarily</p> <p>3 always get a fracture, so there's not an exact</p> <p>4 relationship there, and if you get a fracture you don't</p> <p>5 always have a tilt beforehand. But certainly each --</p> <p>6 the tilting event can exacerbate the possibility of</p> <p>7 fracture.</p> <p>8 So it doesn't make it any safer, but it doesn't</p> <p>9 guarantee -- so this -- it's the same story. There's a</p> <p>10 series of phenomenon that can interact in a synergistic</p> <p>11 fashion to lead to certain other events, but --</p> <p>12 Q. So your definition of the word "exact" means</p> <p>13 every time.</p> <p>14 A. Yeah, for precise kind -- see, what I've found</p> <p>15 a little bit difficult is people saying, "Well, you</p> <p>16 know, there's been a whole bunch of these filters that</p> <p>17 perforated but they didn't fracture; therefore</p> <p>18 perforation and fracture are not coupled." That's an</p> <p>19 imprecise statement.</p> <p>20 Q. Right. But what you can say is that -- strike</p> <p>21 that.</p> <p>22 What you can say, to a reasonable degree of</p> <p>23 scientific and engineering certainty, is that there is a</p> <p>24 relationship of tilt and fracture.</p> <p>25 A. That's what the data that we have now seems to</p>

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<p style="text-align: right;">Page 154</p> <p>1 suggest, from several different sources, and so I would</p> <p>2 say yes, definitely.</p> <p>3 Q. Okay. And you can also say, to a reasonable</p> <p>4 degree of scientific and engineering certainty, that</p> <p>5 there would be -- if there was a tilt, there would be an</p> <p>6 increase in likelihood of fracture to the filter,</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. And vice-versa? In other words, if there was a</p> <p>10 fracture, if a leg fractured off --</p> <p>11 A. Yes, yes.</p> <p>12 Q. -- you can say, to a reasonable degree of</p> <p>13 scientific and engineering certainty, that that could --</p> <p>14 increases the likelihood of tilt?</p> <p>15 A. Yes.</p> <p>16 Q. Because the filter is less stable.</p> <p>17 A. Of course, yes, yes.</p> <p>18 Q. Right.</p> <p>19 A. This is because of the imprecise interface</p> <p>20 between law and engineering.</p> <p>21 Q. Talking about word choice?</p> <p>22 A. Yes.</p> <p>23 Q. I understand. Were you aware that the Simon</p> <p>24 Nitinol filter was the predicate device to the Recovery</p> <p>25 filter?</p>	<p style="text-align: right;">Page 156</p> <p>1 A. Initially, yes.</p> <p>2 Q. And it's still -- the Recovery, the G2, the</p> <p>3 G2-X, the Meridian -- or the Eclipse, the Meridian and</p> <p>4 the Denali are all permanent filters with the option to</p> <p>5 retrieve them?</p> <p>6 A. Correct, yes.</p> <p>7 Q. So they're all permanent filters.</p> <p>8 A. Yes.</p> <p>9 Q. So would it be fair to say the Simon Nitinol</p> <p>10 filter is the safer alternative amongst the other</p> <p>11 filters?</p> <p>12 MS. DALY: Object to form; lack of foundation.</p> <p>13 THE DEPONENT: Yeah, I mean, I only have -- I</p> <p>14 can just recall looking at failure rates and so forth,</p> <p>15 and certainly the Recovery in G2s seem to have more</p> <p>16 problems than the Simon Nitinol filter.</p> <p>17 Q. (By Mr. Dalimonte) So your answer is "yes"?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Do you need to actually conduct a bench</p> <p>20 test to determine that there's the Bard IVC filter line,</p> <p>21 the Recovery G2, Eclipse, and stick with the Meridian,</p> <p>22 are defectively designed?</p> <p>23 A. Well, it's -- it's -- I mean, essentially no,</p> <p>24 but it's nice to have; it's always good -- I'm an</p> <p>25 experimentist. I like to look at something, right? And</p>
<p style="text-align: right;">Page 155</p> <p>1 A. Indeed, yes.</p> <p>2 Q. And so Bard used the Simon Nitinol filter as</p> <p>3 the device that it was modifying under the FDA 510K?</p> <p>4 A. I'm aware of that, yes.</p> <p>5 Q. So they had to represent to the FDA that the</p> <p>6 Recovery filter was safer and more effective than the</p> <p>7 Simon Nitinol filter, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And it had to be the substantial equivalent?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And is it your opinion, to a reasonable</p> <p>12 degree of scientific and engineering certainty, and your</p> <p>13 familiarity with the Bard IVC filter line -- was the</p> <p>14 Recovery filter safer and more efficacious than the</p> <p>15 Simon Nitinol filter?</p> <p>16 A. Well, the -- you know, as I understood the</p> <p>17 situations with respect to adverse events, that doesn't</p> <p>18 seem to be borne out by the data. I have a personal</p> <p>19 opinion on this as well. I think --</p> <p>20 Q. Well, let's just stick to the question.</p> <p>21 A. Okay, but --</p> <p>22 Q. Hold on. So you're aware that the Simon</p> <p>23 Nitinol filter is a permanent filter.</p> <p>24 A. I am, indeed.</p> <p>25 Q. And the Recovery filter was also permanent.</p>	<p style="text-align: right;">Page 157</p> <p>1 I'm having to rely on reading documents and so forth</p> <p>2 about the design, but certainly the G2, G2-Express, the</p> <p>3 Eclipse and the Meridian have an essentially similar</p> <p>4 design, with a few little differences I've talked about.</p> <p>5 So it's hard to believe that there would be radical</p> <p>6 changes in the function that caused the problems.</p> <p>7 Now, obviously, the fact that after the</p> <p>8 Eclipse, that the electropolish, that will alleviate one</p> <p>9 aspect. But you don't need to actually touch one, but I</p> <p>10 -- you know, when it comes to looking at fracture, I</p> <p>11 like to be able to see a fracture mode, so it's nice to</p> <p>12 be able to have the part. And from the perspective of</p> <p>13 do I expect this to have a similar set of problems or</p> <p>14 something like that, you don't really need to see it for</p> <p>15 that reason.</p> <p>16 Q. Well, yeah, you talked about what you do, what</p> <p>17 you teach and what you do for the industry.</p> <p>18 A. Yeah.</p> <p>19 Q. And if there are certain failure modes being</p> <p>20 reported, you know there's a problem.</p> <p>21 A. Yeah. I mean, I work on nuclear graphite, but</p> <p>22 I don't crawl on nuclear reactors just to be able to get</p> <p>23 my hands on them. Obviously, an experimentist likes to</p> <p>24 see something, but it's not an essential thing.</p> <p>25 Q. It just provides that added confidence, right?</p>

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<p style="text-align: right;">Page 158</p> <p>1 A. But, I mean, when you're looking at fractures, 2 it's nice to have looked at the fracture. But, yes, of 3 course, something. 4 Q. And without actually conducting a bench test, 5 that doesn't affect your opinion to -- any of your 6 opinions, to a reasonable degree of scientific and 7 engineering certainty, correct? 8 A. A bench test would be a tested device, right? 9 Q. I'm sorry, what? 10 A. A bench -- 11 Q. Yes, yes, correct. So let me repeat the 12 question so the record is clear. 13 You do not need to conduct a bench test -- 14 well, a bench test, lack of a bench test -- well, strike 15 that, because I asked the question perfectly the first 16 time. 17 Your opinions, to a reasonable degree of 18 scientific and engineering certainty, are not affected 19 in any way by the fact that you personally didn't do any 20 type of bench tests, correct? 21 A. No. 22 Q. Is that right? 23 A. That's right, yeah. 24 Q. And you also had the benefit of reviewing all 25 of the tests that Bard did on their filters, correct?</p>	<p style="text-align: right;">Page 160</p> <p>1 (Recess) 2 VIDEOGRAPHER: We are back on the record. The 3 time is 2:51 p.m. 4 REDIRECT EXAMINATION BY 5 MS. DALY: Q. Dr. Ritchie, just a couple of 6 questions. Going back to the testing -- 7 A. Yeah. 8 Q. -- which was the last thing Mr. Dalimonte asked 9 you about, is it your understanding that Bard did not do 10 testing which resulted in taking the filter to a point 11 that it fractured or migrated or tilted? 12 A. Well, to some degree that's true, because the 13 medical industry works on survival rather than failure, 14 which is not a good thing. But my main point is if you 15 have a bench test, you need to somehow simulate the 16 reality of your situation, which can be a path en vivo. 17 And if you're suffering whatever it may be, tilt or what 18 have you; you need to have a bench test that somehow 19 reflects that. 20 And to have a bench test where you do something 21 and it passes every time yet the reality is clearly not 22 doing that, tells you that your bench test is really not 23 reflective of the situation. So in some respects, some 24 of those bench tests are a complete waste of time. 25 Q. But you are aware that they did testing of</p>
<p style="text-align: right;">Page 159</p> <p>1 A. Yeah, I've looked at all of them at some time 2 over the last several years. 3 Q. And you testified earlier to Ms. Daly's 4 questions as to what Bard needed to do as far as 5 matching their bench test results, which were coming 6 back with this filter's passing, with real life problems 7 that are being reported, you know, to the FDA, to the 8 manufacturer about failures and adverse events 9 associated with their product. 10 A. Well, I think the bench tests that a company 11 develops before and during the process of selling their 12 component, whatever it may be, if they're suffering 13 adverse events in practice, then they need to find the 14 source of that and they need to find a bench test that 15 can simulate it. 16 I think doing bench tests which -- which were 17 their components would largely pass and yet the reality 18 is that they're failing in practice, there's something 19 wrong with that picture. So I've been critical of a lot 20 of the tests that Bard did, because they never had a 21 failure. 22 Q. Give me a minute. I might be done. Can we go 23 off the record? 24 VIDEOGRAPHER: We're off the record at 2:47 25 p.m.</p>	<p style="text-align: right;">Page 161</p> <p>1 filters to actual failure, where they -- 2 A. Of course, yes, and that was good, that was 3 good, but -- 4 Q. And you're aware that they did testing where 5 they tilted a filter to see would happen to it -- 6 A. Yes. 7 Q. -- and that they tested a filter until they 8 could make it migrate. 9 A. Yes, but -- and that was good, but, you know, 10 they -- to me, my way of thinking, they had sort of -- 11 they -- they chose, for example, for migration, to lower 12 pressure, and they had things that were migrating just a 13 little bit higher pressure in their tests, and -- and 14 yet they had a problem with migration in reality. 15 So I think the bench tests that were done from 16 the very beginning should have somehow sought to -- to 17 reflect some of the problems that they were seeing. And 18 I think that the function of these filters was somewhat 19 abnormal to them. And that's okay initially, because -- 20 you know, to understand that, but there was a long 21 history where this -- where it wasn't dealt with; I 22 think that was the issue. That's my only query about 23 that. 24 Q. And as we talked about before, you have not, in 25 your role in this case, tried to fashion what those</p>

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<p style="text-align: right;">Page 162</p> <p>1 tests would be.</p> <p>2 A. Well, you know, no, that would not be my</p> <p>3 position, but I think they should have done so.</p> <p>4 Q. All right. You were asked a series of</p> <p>5 questions about reasonable engineering certainties.</p> <p>6 A. Yeah.</p> <p>7 Q. Let me just -- let me clarify this in my own</p> <p>8 mind. What I think you're saying is you can not, within</p> <p>9 a reasonable engineering certainty -- hold it. Let me</p> <p>10 say this right.</p> <p>11 Okay. You can not, within a reasonable</p> <p>12 engineering certainty, say what the likelihood is of</p> <p>13 occurrence of a particular type of complication in a</p> <p>14 particular filter.</p> <p>15 A. In a particular --</p> <p>16 MR. DALIMONTE: Objection.</p> <p>17 THE DEPONENT: A given filter or a particular</p> <p>18 type of filter?</p> <p>19 Q. (By Ms. Daly) You can't say that there is a</p> <p>20 increased likelihood --</p> <p>21 A. Yes.</p> <p>22 Q. -- of complications generally.</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Also you can not say, within a</p> <p>25 reasonable engineering certainty, what the relative</p>	<p style="text-align: right;">Page 164</p> <p>1 Q. (By Ms. Daly) It is that tricky, isn't it?</p> <p>2 A. It's that tricky. God.</p> <p>3 Now, the thing that I object to is saying that</p> <p>4 since something failed by fracture and didn't penetrate,</p> <p>5 therefore penetration and fracture are not related. So</p> <p>6 -- so the quality is true that there is a relationship,</p> <p>7 but it needn't be seen because other things can happen</p> <p>8 -- this is --</p> <p>9 Q. I think we're on the same page.</p> <p>10 A. We're on the page. How people interpret it is</p> <p>11 another issue.</p> <p>12 RE-CROSS-EXAMINATION BY</p> <p>13 MR. DALIMONTE: Q. Getting back to Ms. Daly's</p> <p>14 last question on the occurrences, what you can say is</p> <p>15 that these particular filters, to a reasonable degree of</p> <p>16 scientific and engineering certainty, have a greater</p> <p>17 likelihood of failure in comparison to its intended use</p> <p>18 and the safe use of the product itself.</p> <p>19 A. I think that's a very reasonable statement.</p> <p>20 Q. And so it doesn't matter what the occurrence</p> <p>21 rates are; what matters is that there are multiple</p> <p>22 variables, multiple adverse events. You could have a</p> <p>23 filter with a migration, tilt, perforation, fracture,</p> <p>24 filter embolization all in one device, correct?</p> <p>25 A. That's right.</p>
<p style="text-align: right;">Page 163</p> <p>1 increased likelihood would be for any particular</p> <p>2 complication to occur in each of the various models of</p> <p>3 Bard filters.</p> <p>4 A. Well, this is difficult to answer. The -- the</p> <p>5 -- no, you can't give a precise number. Now, you could</p> <p>6 try to do that by using calculations or using</p> <p>7 statistics, but I think it would be very, very difficult</p> <p>8 to have a preciseness there.</p> <p>9 So with these words, "reasonable degree of</p> <p>10 engineering certainty," you can say the likelihood of a</p> <p>11 certain type of fracture would increase, but there's so</p> <p>12 many imponderables in the body and so forth, you -- it</p> <p>13 would be very difficult to say there's a 60 percent</p> <p>14 increase in positive tilting.</p> <p>15 Q. Also the next set that Mr. Dalimonte was asking</p> <p>16 you about, within a reasonable engineering certainty,</p> <p>17 you can say that there is a relationship between various</p> <p>18 complications like tilt and perforation or fracture and</p> <p>19 perforation, correct?</p> <p>20 A. That's right, yes.</p> <p>21 Q. All right. You can not say, within a</p> <p>22 reasonable engineering certainty, what combination of</p> <p>23 those relationships of complication will lead to another</p> <p>24 complication.</p> <p>25 MR. DALIMONTE: Objection.</p>	<p style="text-align: right;">Page 165</p> <p>1 MS. DALY: Object to form.</p> <p>2 Q. (By Mr. Dalimonte) And you could also have any</p> <p>3 number of combinations of it.</p> <p>4 A. Yes.</p> <p>5 Q. Is that right?</p> <p>6 A. That's right.</p> <p>7 Q. And what you don't do is you don't count -- you</p> <p>8 separate them all out and put them in different</p> <p>9 categories and try to tell the public that their adverse</p> <p>10 event rate is lower than anybody else's, right?</p> <p>11 MS. DALY: Object to the form.</p> <p>12 Q. (By Mr. Dalimonte) In other words, if you have</p> <p>13 a filter that has a fracture alone and another filter</p> <p>14 that has a migration, you don't say, "Well, we only had</p> <p>15 one adverse event in each category," correct?</p> <p>16 MS. DALY: Object to the form, lack of</p> <p>17 foundation, and outside the scope of his reports.</p> <p>18 Q. (By Mr. Dalimonte) Okay, well, Ms. Daly asked</p> <p>19 you a number of questions on occurrences, and that's why</p> <p>20 we have a biostatistician, right?</p> <p>21 A. Well, the -- I mean, I think the numbers of</p> <p>22 occurrences are just based on what people have looked</p> <p>23 at, this one failed by that and that one failed by that.</p> <p>24 That's a different -- that's a more definitive</p> <p>25 statement, and statisticians can do what they have with</p>

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<p>1 this.</p> <p>2 What we're talking about is what is the</p> <p>3 mechanistic cause of failures and how the various</p> <p>4 different features link together, and that's a much more</p> <p>5 complicated process. And so you can -- all you can say,</p> <p>6 and you can say this to more than a reasonable doubt, is</p> <p>7 that --</p> <p>8 Q. Reasonable degree of scientific certainty.</p> <p>9 A. Whatever it is --</p> <p>10 Q. That's all right.</p> <p>11 A. But if -- if there's a -- if there's a stress</p> <p>12 concentration there, for example, then there will be a</p> <p>13 higher stress, and therefore the likelihood of fracture</p> <p>14 in that event is increased. It may not fracture there</p> <p>15 because something might happen somewhere else, but that</p> <p>16 is an absolute given, right? So that's what I'm saying</p> <p>17 here, is that some of them are very definitive.</p> <p>18 Others where, for example, if you have a</p> <p>19 perforation, it seems certainly more than likely that</p> <p>20 you're going to elevate the stresses, and when</p> <p>21 something's constrained by that -- and there's evidence</p> <p>22 now from mathematical calculations that supports that.</p> <p>23 So, again, that's a statement you can say, to a</p> <p>24 reasonable degree of scientific doubt -- scientific and</p> <p>25 engineering certainty, that there will be an increased</p>	<p>1 STATE OF CALIFORNIA ) ss.</p> <p>2</p> <p>3 I hereby certify that the deponent in the foregoing</p> <p>4 deposition was by me duly sworn to testify to tell the</p> <p>5 truth, the whole truth and nothing but the truth in the</p> <p>6 within-entitled cause; that said deposition was taken at</p> <p>7 the time and place therein stated; that the deposition</p> <p>8 is a true record of the deponent's testimony as reported</p> <p>9 to the best of my ability by me, a duly certified</p> <p>10 shorthand reporter and a disinterested person, and was</p> <p>11 thereafter transcribed under my direction into</p> <p>12 typewriting by computer.</p> <p>13 I further certify that I am not interested in</p> <p>14 the outcome of the said action, nor connected with, nor</p> <p>15 related to any of the parties in said action, nor to</p> <p>16 their respective counsel</p> <p>17 IN WITNESS WHEREOF, I have hereunto set my hand</p> <p>18 this 21st day of June, 2017.</p> <p>19</p> <p>20</p> <p>21</p> <p>22 </p> <p>23</p> <p>24 JILL ANNE STEPHENSON, CSR 8563</p> <p>25</p>
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<p>1 chance of a fracture. But to say a given filter will</p> <p>2 fracture because it has a perforation is, obviously,</p> <p>3 something you can't say, a given filter.</p> <p>4 Q. Understood.</p> <p>5 MS. DALY: You can't say.</p> <p>6 THE DEPONENT: You can't say.</p> <p>7 MR. DALIMONTE: Understood.</p> <p>8 MS. DALY: We're good.</p> <p>9 MR. DALIMONTE: Thank you.</p> <p>10 VIDEOGRAPHER: This marks the end of Disk No. 3</p> <p>11 and today's testimony of Robert O. Ritchie, Ph.D. We're</p> <p>12 off the record at 3:00 o'clock p.m.</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	

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# **EXHIBIT D**

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SUPERIOR COURT OF THE STATE OF ARIZONA  
IN AND FOR THE COUNTY OF MARICOPA

KATRINA NEWTON, et al.,

Plaintiff,

-vs-

CASE NO. CV2009-019232  
CV2009-035787

C.R. BARD, et al.,  
Defendants.

RICHARK KOLENDA, et al.,  
Plaintiff,

-vs-

C.R. BARD, et al.,  
Defendants.

VIDEODEPOSITION OF ROBERT O. RITCHIE, PH.D.  
May 23, 2011

REPORTER'S TRANSCRIPT OF PROCEEDINGS  
BY: JOANNA BROADWELL, CSR 10959

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Examination by:

Page

Mr. North

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Also appearing: Stephen Statler, Videographer.  
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<p>1 BE IT REMEMBERED that, pursuant to Notice of 2 Taking Deposition, and on Monday, May 23, 2011, 3 commencing at the hour of 9:20 a.m. at the offices of 4 Clark Reporting and Videoconferencing, 2140 Shattuck 5 Avenue, Suite 405, Berkeley, California, before me, 6 JOANNA BROADWELL, a duly qualified Certified Shorthand 7 Reporter, License No. 10959, in and for the State of 8 California, there personally appeared 9 ROBERT O. RITCHIE, PH.D. 10 called as a witness by the Defendants, who, being first 11 duly sworn by me to tell the truth under penalty of 12 perjury under the laws of the State of California, was 13 thereupon examined and testified as hereinafter set forth. 14 --o0o-- 15 PROCEEDINGS 16 THE VIDEOGRAPHER: Here begins the Video No. 1 17 of the deposition of Robert Ritchie, Ph.D. in the 18 matter of Katrina Newton, et al., versus C.R. Bard, 19 Incorporated, et al. and related actions in the 20 Superior Court of the State of Arizona for the County 21 of Maricopa. The case numbers are CV2009-019232 and 22 CV2009-035781. Today's date is May 23rd, 2011, and the 23 time on the video monitor is 9:20 a.m. 24 The video operator today is Stephen Statler, 25 representing Clark Reporting and Videoconferencing.</p>	<p>1 MR. NORTH: I would like to propose that we 2 reserve all objections except as to the form of the 3 question and responsiveness of the answer until such 4 time as this deposition may be used. 5 MR. HARTLEY: That is fine. 6 MR. NORTH: Have you discussed signature with 7 the witness? 8 MR. HARTLEY: We haven't. 9 Doctor, do you want to read and sign? 10 THE DEPONENT: I beg your pardon? 11 MR. HARTLEY: Do you want to read and sign 12 your deposition? 13 THE DEPONENT: Sure. Absolutely. 14 MR. HARTLEY: He just answered that. 15 EXAMINATION BY COUNSEL FOR THE DEFENDANTS 16 BY MR. NORTH 17 Q. Could you state your full name for the record? 18 A. My name is Robert Oliver Ritchie. 19 Q. Dr. Ritchie, as I introduced myself a few 20 moments ago, my name is Richard North, and I represent 21 the Defendant C.R. Bard, and Bard Peripheral Vascular 22 in the litigation which brings us here today. 23 Today I am going to be asking you a series of 24 questions about your involvement in that litigation. 25 If at any time I ask you a question that you do not</p>
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<p>1 This videodeposition is taking place at 2140 Shattuck 2 Avenue in Berkeley, California. 3 Counsel, please voice-identify yourself and 4 state who you represent. 5 MR. HARTLEY: Dean Hartley on behalf of the 6 Plaintiffs. 7 MR. NORTH: Richard North on behalf of the 8 Defendants Bard, C.R. Bard, and Bard Peripheral 9 Vascular. 10 MS. HELM: Kate Helm on behalf of the same 11 defendants. 12 THE VIDEOGRAPHER: Thank you. The court 13 reporter today is Joanna Broadwell of Clark Reporting 14 and Videoconferencing. And would the reporter please 15 administer the oath? 16 (The Witness was sworn.) 17 THE VIDEOGRAPHER: Please begin. 18 MR. NORTH: This will be the deposition of 19 Robert O. Ritchie, taken for purposes of discovery and 20 all other purposes permitted under the Arizona and 21 Federal Rules. Mr. Hartley, just so the record is 22 clear, I believe we have agreed that this deposition 23 will be utilized in all cases in which Dr. Ritchie has 24 been designated as an expert. 25 MR. HARTLEY: Yes.</p>	<p>1 hear or do not understand, please ask me to repeat it 2 or rephrase it. Is that agreeable? 3 A. Yes, indeed. 4 Q. If at any time you would like to take a break, 5 just let us know. This is not an endurance contest. 6 We are happy to take a break. Okay? 7 A. Surely. 8 Q. And I would ask also that you answer all 9 questions out loud, as opposed to a nod of the head or 10 "uh-huh" or "huh-uh" so that the court reporter can 11 prepare an accurate transcript for us. 12 A. Fair enough. 13 Q. Could you tell us your present business 14 address? 15 A. My -- I am a professor of material science 16 engineering at the University of California. So my 17 business address is the Department of Material Science 18 and Engineering, University of California, Berkeley. 19 MR. HARTLEY: Could you hear him? Is it 20 coming through all right? 21 BY MR. NORTH 22 Q. Dr. Ritchie, have you ever given a deposition 23 before? 24 A. Yes, I have. 25 Q. On how many occasions?</p>

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DEPOSITION OF ROBERT O. RITCHIE, PH.D.

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<p>1 A. Four or five. Five or so.</p> <p>2 Q. When is the last time you gave a deposition?</p> <p>3 A. About four years ago -- four or five years</p> <p>4 ago.</p> <p>5 Q. Have all of your depositions been given in the</p> <p>6 role of an expert witness?</p> <p>7 A. Yes, indeed.</p> <p>8 Q. Have you ever testified live at trial?</p> <p>9 A. Yes, indeed.</p> <p>10 Q. On how many occasions?</p> <p>11 A. I think twice, maybe three times. I think</p> <p>12 twice.</p> <p>13 Q. In the cases that you have testified live at</p> <p>14 trial, have you -- did those involve personal injury</p> <p>15 cases or patent cases?</p> <p>16 A. They were personal injury. I have been</p> <p>17 involved in patent cases, but none came to trial.</p> <p>18 Q. I'm sorry. I am having a hard time finding</p> <p>19 this curriculum vitae.</p> <p>20 A. I can give you a copy.</p> <p>21 Q. Do you have one with you? That would be</p> <p>22 great.</p> <p>23 A. There you go.</p> <p>24 Q. What is this booklet that you have just handed</p> <p>25 us?</p>	<p>1 update this quite regularly, so I think it is the same</p> <p>2 version.</p> <p>3 Q. Mr. Hartley, I believe we agreed we can</p> <p>4 substitute a clean copy without my markings on it as an</p> <p>5 exhibit to this deposition.</p> <p>6 MR. HARTLEY: Yes.</p> <p>7 BY MR. NORTH</p> <p>8 Q. Dr. Ritchie, as I understand it, you have a</p> <p>9 bachelor's degree in metallurgy and physics?</p> <p>10 A. Yes, indeed.</p> <p>11 Q. That is from Cambridge University?</p> <p>12 A. Yes.</p> <p>13 Q. And that's Cambridge in England?</p> <p>14 A. That's Cambridge in England.</p> <p>15 Q. Are you originally from England?</p> <p>16 A. I am, indeed.</p> <p>17 Q. What part of England did you grow up in?</p> <p>18 A. Plymouth.</p> <p>19 Q. You also have a master's in material science</p> <p>20 and a Ph.D. from Cambridge?</p> <p>21 A. Yes, indeed.</p> <p>22 Q. And I believe your Ph.D. was in 1973?</p> <p>23 A. That's right.</p> <p>24 Q. Now, there is another degree listed on your</p> <p>25 curriculum vitae in 1990 from Cambridge. What is that?</p>
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<p>1 A. It's a document which contains all my reports.</p> <p>2 Q. And did you compile this document yourself?</p> <p>3 A. I wrote it, but I didn't compile it, no.</p> <p>4 Q. Okay. You don't have a loose version of your</p> <p>5 curriculum vitae with you, do you? I don't think that</p> <p>6 or his report is in here. I tell you what, what I</p> <p>7 would like to do is have marked as an Exhibit 1 to this</p> <p>8 deposition -- I have a copy of your curriculum vitae.</p> <p>9 It has got some scribbling on it; maybe we could just</p> <p>10 substitute a clean copy at a later time.</p> <p>11 A. Sure. That is fine.</p> <p>12 MR. HARTLEY: Do you want him to refer to the</p> <p>13 one that is bound so that you don't --</p> <p>14 MR. NORTH: Yeah, that is fine.</p> <p>15 (Whereupon Defendants' Exhibit No.</p> <p>16 1 was marked for identification.)</p> <p>17 MR. NORTH: If we could mark this as</p> <p>18 Exhibit 1.</p> <p>19 Q. Doctor, let me show you what's been marked as</p> <p>20 Exhibit 1. Does that appear to be a copy of your</p> <p>21 curriculum vitae, albeit with some scribbling on it?</p> <p>22 A. Yes.</p> <p>23 Q. And you have another copy of that in front of</p> <p>24 you?</p> <p>25 A. I think it is the exact -- I don't know. I</p>	<p>1 A. It is quite a Doctor of Science. There is no</p> <p>2 equivalent in this country, but a Ph.D. is given for a</p> <p>3 single piece of research, and a doctorate of science is</p> <p>4 given for a lifetime of research, so it is a higher</p> <p>5 degree than a Ph.D.</p> <p>6 Q. Did you -- I mean, obviously the Doctor of</p> <p>7 Sciences was -- was bestowed on you some 17 years after</p> <p>8 your Ph.D.?</p> <p>9 A. Yes.</p> <p>10 Q. Did you go back to Cambridge for additional</p> <p>11 courses for that?</p> <p>12 A. No, no. What one does is one submits -- when</p> <p>13 asked, one submits all your published work. And then</p> <p>14 the University appoints a committee to examine it. And</p> <p>15 they charge you 400 guineas, and then they make a</p> <p>16 decision about it. So...</p> <p>17 MR. HARTLEY: You have to ask how much is a</p> <p>18 guinea.</p> <p>19 BY MR. NORTH</p> <p>20 Q. How much is a guinea?</p> <p>21 A. One pound, one shilling.</p> <p>22 Q. Okay.</p> <p>23 A. And it enables you to wear a rather fancy</p> <p>24 gown.</p> <p>25 Q. My understanding is, there is no equivalent to</p>

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<p>1 that degree in this country?</p> <p>2 A. No, there is no equivalent in this country.</p> <p>3 Q. Following the receipt of your Ph.D. in 1973,</p> <p>4 have you taken any other formal training since that</p> <p>5 time?</p> <p>6 A. Well, I was -- it depends on what you call</p> <p>7 that, but I was a postdoctoral researcher in Cambridge,</p> <p>8 and then I came to Berkeley as what's called a Miller</p> <p>9 Postdoctoral Fellow. And I did that until 1977 to '76,</p> <p>10 actually. Then I joined the faculty at M.I.T.</p> <p>11 Q. So I believe your first job around the time</p> <p>12 that you did get your Ph.D. was this postdoctoral</p> <p>13 fellow at Cambridge?</p> <p>14 A. Yeah. I was what is called a Goldsmith's</p> <p>15 Junior Research Fellow in Churchill College, Cambridge.</p> <p>16 Q. What does that connote, the Goldsmith's Junior</p> <p>17 Research Fellow?</p> <p>18 A. It is basically -- It's the equivalent of a --</p> <p>19 a slightly different system in England, but it is</p> <p>20 equivalent of a faculty position at a junior level. So</p> <p>21 I was a Fellow -- a Fellow at one of the Cambridge</p> <p>22 colleges. And I did that for two years and then took a</p> <p>23 year off to go to America and never came home.</p> <p>24 Q. Did you -- during that two years at Cambridge</p> <p>25 in that position, did you actually teach students?</p>	<p>1 A. I taught a course on the mechanical behavior</p> <p>2 of materials. It was on -- it was basically a</p> <p>3 sophomore-junior class on how materials fail, the</p> <p>4 deformation and fracture properties.</p> <p>5 Q. And then in 1977, I understand that you left</p> <p>6 Berkeley for a stint at M.I.T. in Cambridge,</p> <p>7 Massachusetts?</p> <p>8 A. Yeah, I joined the faculty of mechanical</p> <p>9 engineering at M.I.T. and was an assistant professor</p> <p>10 there, and then I was an associate professor there, and</p> <p>11 then I became what is called a Class of 1922 Associate</p> <p>12 Professor. I was there until 1981.</p> <p>13 Q. Why did you leave M.I.T.?</p> <p>14 A. Because I hated the place.</p> <p>15 Q. Okay.</p> <p>16 A. I am being a bit flippant there, but I believe</p> <p>17 education is interaction with all disciplines, having</p> <p>18 lunch with a philosopher and tea with historians.</p> <p>19 M.I.T. is a place full of engineers, and the weather</p> <p>20 sucks in Boston.</p> <p>21 MR. NORTH: Has Dr. Ritchie been designated in</p> <p>22 the John Long case?</p> <p>23 Q. Okay. You returned to Berkeley in 1981?</p> <p>24 A. Indeed.</p> <p>25 Q. And what position did you take when you came</p>
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<p>1 A. Well, I gave what is called supervisions. I</p> <p>2 didn't -- I didn't give -- I didn't have a classroom</p> <p>3 that I taught in groups of students. It is called a</p> <p>4 supervision format. It is, again, different in this</p> <p>5 country, but there are lecturers and there are</p> <p>6 supervisors, and I acted in a supervisory capacity. I</p> <p>7 also taught lab classes. But I wasn't a member of the</p> <p>8 faculty. I was a Fellow of the college.</p> <p>9 Q. Did you do any research during that two years?</p> <p>10 A. I was doing research the whole time.</p> <p>11 Q. And then in 1974, you moved to Berkeley?</p> <p>12 A. I moved to Berkeley, yes.</p> <p>13 Q. What was your position -- I believe your first</p> <p>14 stint here at Berkeley was from '74 to '77?</p> <p>15 A. Yeah. It was -- I left in -- in January '77.</p> <p>16 I was what is called a Miller Research Fellow, which is</p> <p>17 a -- they award five or six of these a year. And that</p> <p>18 brought me to Berkeley. And as a Miller research</p> <p>19 fellow I continued my research. I also taught courses</p> <p>20 at this time. I taught several courses.</p> <p>21 Q. What sorts of research projects were you</p> <p>22 working on generally during your three years at</p> <p>23 Berkeley?</p> <p>24 A. I was working on fracture and fatigue.</p> <p>25 Q. What sort of classes were you teaching?</p>	<p>1 back to Berkeley?</p> <p>2 A. I came back, actually, in what is called an</p> <p>3 Acting Associate Professor of Material Science and</p> <p>4 Engineering, and then I became a full professor a year</p> <p>5 later.</p> <p>6 Q. What is the difference in -- between an Acting</p> <p>7 Associate Professor and an Associate Professor?</p> <p>8 A. It was a -- it is a long story, but basically</p> <p>9 the University here only had a junior position, and I</p> <p>10 had a relatively senior position at MIT. So the</p> <p>11 "Acting" was a way of getting me in without demeaning</p> <p>12 my stature. And I agreed to do it, provided they put</p> <p>13 me up for a full professor within the year, no</p> <p>14 guarantees, and which they did.</p> <p>15 Q. And so you became a full Professor of Material</p> <p>16 Science and Engineering in 1982?</p> <p>17 A. I did, yes.</p> <p>18 Q. And that is still a position you hold today;</p> <p>19 is that correct?</p> <p>20 A. Yes, I am head of department now. But, yes.</p> <p>21 Q. And you became Chairman of the department in</p> <p>22 2005?</p> <p>23 A. Yes.</p> <p>24 Q. And I also see some indication that beginning</p> <p>25 in 2010, you had the title Professor of Mechanical</p>

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<p>1 Engineering?</p> <p>2 A. Yeah. I was made a member of the Mechanical</p> <p>3 Engineering Department last year. Yes.</p> <p>4 Q. So are you simultaneously part of the</p> <p>5 Mechanical Engineering Department and the Material</p> <p>6 Science and Engineering Department?</p> <p>7 A. I am, indeed.</p> <p>8 Q. My assumption is, they would be pretty closely</p> <p>9 aligned anyway, wouldn't they, those two departments?</p> <p>10 A. In principle, yes, in reality, often no.</p> <p>11 Q. Okay. Now, I gather you have been affiliated</p> <p>12 with the Lawrence Berkeley Laboratory since your return</p> <p>13 to Berkeley in 1981 or '82?</p> <p>14 A. Yes. I have a position up there, and I have</p> <p>15 in the past actually had a -- you know, a more</p> <p>16 permanent position. I was half time at one stage. But</p> <p>17 yes, I have an appointment.</p> <p>18 Q. Well, just for my benefit, what is the</p> <p>19 Lawrence Berkeley Laboratory?</p> <p>20 A. It is one of the system of national labs. You</p> <p>21 have Oak Ridge Argonne and Brookhaven. It was actually</p> <p>22 the first national lab. It was administered by the</p> <p>23 University of California; however, it is a totally</p> <p>24 separate entity. It is akin to another campus of the</p> <p>25 University of California. It is a federally-funded</p>	<p>1 A. Nor is Oak Ridge, for that matter, anymore.</p> <p>2 It's just like Livermore would be or Sandia for weapons</p> <p>3 labs. Lawrence Berkeley Lab is like Oak Ridge: It is</p> <p>4 a general national lab. It is focused -- very focused</p> <p>5 on the science rather than the engineering, though. It</p> <p>6 has a heavy emphasis on physics and chemistry and</p> <p>7 material science. And these national labs now are more</p> <p>8 characterized by their facilities.</p> <p>9 We have a synchrotron up there, which is</p> <p>10 the -- and we have the National Computing Center, and</p> <p>11 the National Center for Electron Microscopy. So that</p> <p>12 is where the focus is, the emphasis of the lab. Oak</p> <p>13 Ridge always has been more of a technological place,</p> <p>14 more attuned to industrial concerns than LBL.</p> <p>15 Q. These labs don't actually specialize in</p> <p>16 producing inventions, or do they?</p> <p>17 A. Well, they do generate inventions. A large</p> <p>18 number of them do. I mean, there is IR awards every</p> <p>19 year for inventions, and the Lawrence Lab, like most</p> <p>20 national labs, will win three or four of them every</p> <p>21 year. But it is not geared specifically to do that.</p> <p>22 Q. Do you still maintain some affiliation with</p> <p>23 the Lawrence Berkeley Lab?</p> <p>24 A. All of my labs are up there. All my research</p> <p>25 is done up there. So I am paid by the University,</p>
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<p>1 lab, primarily by the Department of Energy. Its</p> <p>2 relationship to Berkeley, the University, is merely of</p> <p>3 its close proximity.</p> <p>4 Q. But you said that it is supervised somehow by</p> <p>5 the California University system --</p> <p>6 A. It is administered by University of</p> <p>7 California, but they play a rather standoffish role.</p> <p>8 They ran Los Alamos and Livermore. The ties with</p> <p>9 University of -- were broken a few years ago with those</p> <p>10 labs. They are now run by an industrial consortium.</p> <p>11 LBL -- LBNL is still administered by the University of</p> <p>12 California. So it's -- you can think of it like a</p> <p>13 separate campus, but it is federally funded as opposed</p> <p>14 to state funded.</p> <p>15 Q. Now, I grew up not far from Oak Ridge, so I am</p> <p>16 familiar with that, and we all know, I think, that Oak</p> <p>17 Ridge National Laboratory was the site, as I understand</p> <p>18 it, where the nuclear bomb was developed?</p> <p>19 A. There was a number of sites, but that was one</p> <p>20 of them, yes.</p> <p>21 Q. Right. Is there any particular focus of the</p> <p>22 Lawrence Berkeley Laboratory? Does it have any</p> <p>23 specialty?</p> <p>24 A. Well, it is -- it is not a weapons lab.</p> <p>25 Q. Okay.</p>	<p>1 except in the summer when I get a salary from the</p> <p>2 Lawrence Berkeley lab, but I conduct all of my research</p> <p>3 business at LBL.</p> <p>4 Q. So how much of your time in a typical work</p> <p>5 week is spent up at the Lawrence Berkeley Laboratory?</p> <p>6 A. It varies, because I have been head of the</p> <p>7 department. It's kept me down on campus a lot of the</p> <p>8 time. You know, under normal circumstances, I would</p> <p>9 probably spend 60 to 70 percent of my time up at LBL.</p> <p>10 In the last five or six years, it's probably been the</p> <p>11 reverse. It's been closer to 30 to 40 percent.</p> <p>12 Q. And I see that you have held administrative</p> <p>13 positions at the Laboratory in the past?</p> <p>14 A. Yes, I was the Director of the Center for</p> <p>15 Advanced Materials in the '80s and '90s, and I was</p> <p>16 associate -- acting -- sorry -- assistant -- associate</p> <p>17 -- Deputy Director, sorry, of the Materials Division</p> <p>18 for a time in the late '80s and early '90s.</p> <p>19 Q. Do you presently maintain any leadership role</p> <p>20 or administrative role at the laboratory?</p> <p>21 A. I sit on the Scientific Council for the</p> <p>22 Materials Division, and I run a major program, a</p> <p>23 research program up there in materials.</p> <p>24 Q. What is the focus of your research program up</p> <p>25 there at the Laboratory right now?</p>

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<p>1 A. It is focused on fracture and fatigue, 2 primarily. A lot of it is now on some of the newer 3 materials, like metallic glasses. I do work on medical 4 implants, and I work on bio-inspired materials, and 5 although it is not funded by the Department of Energy, 6 I do a lot of work on bone and teeth and biological 7 materials. 8 Q. What sort of medical implants are you doing 9 research work on? 10 A. Well, I work primarily on Nitinol, actually, 11 and I have been looking at the fatigue of Nitinol and 12 various aspects of that for many, many years. So it -- 13 most of it has been Nitinol-focused. I have also 14 looked at materials like the cobalt chrome materials, 15 which is an alternative material for medical device 16 manufacturing. 17 Q. Is that research work focused on Nitinol as a 18 general substance, or on specific types of devices? 19 A. Well, it is -- yes and yes. I mean, it is -- 20 I am interested in the fundamental properties of this 21 material. It is a fascinating material. It is a very 22 different material. But we do a lot of work in the 23 synchrotron doing x-ray diffraction to understand how 24 these materials deform at almost an atomistic level. 25 But most of my funding has come from medical</p>	<p>1 number of companies that are trying to make wire-like 2 heart valves that you could actually implant with a 3 catheter instead of having to break the ribcage, and 4 these would inflate inside the heart. And most of 5 those -- the inflation -- the self-inflating portions 6 are made of Nitinol. 7 Q. But those are not on the market yet, are they? 8 A. There is one of them that's just been -- I'm 9 not sure it's been marketed -- it's just been approved 10 by the Food and Drug Administration. I am working with 11 Edwards on that, and there is another one in Sorin, in 12 Italy, which I am working on, and that one is not -- 13 that's not gone through FDA approval. It's in the 14 process of -- about to be submitted, I believe. 15 Q. Okay. You mentioned Edwards Life Science. 16 And what was the company in Italy? 17 A. Sorin, S-o-r-i-n. 18 Q. What other medical device companies are you 19 presently consulting with? 20 A. St. Jude Medical. 21 Q. I'm sorry, Synergy? 22 A. St. Jude Medical. 23 Q. St. Jude. 24 A. Abbott is about to -- I haven't actually been 25 there yet, but Abbott just called me recently.</p>
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<p>1 device companies, so the focus has been more on the 2 medical device. So I have done work on predicting the 3 life of stents, for example, and looking at how the 4 texture of these materials changes. So most of the 5 emphasis is geared to medical devices. 6 Q. You mentioned stents. What other types of 7 medical devices -- specific medical devices, has your 8 research focused on? 9 A. Well, a lot of it has been on heart valves, 10 but I have looked at all types of medical devices. I 11 have looked at stents. I have looked at various 12 different types of heart valves. I have looked at some 13 of these stent-like devices that close holes in the 14 heart. I have looked at orthopedic implants, knee 15 implants, hip implants. I have looked at aneurysm 16 clips, bone screws, all sorts of -- these are not all 17 Nitinol devices, of course, but I've looked at many 18 different types of medical devices. 19 My interest these days has been more on these 20 wire-type Nitinol devices, like the stent. 21 Q. Obviously there are some stents that are made 22 of Nitinol. 23 A. Oh, yes. 24 Q. Are any of the heart valves made of Nitinol? 25 A. They are starting to be. I am working with a</p>	<p>1 Certainly Cordis, NDC, which is Nitinol Devices 2 Components, Sorin, and Edwards. 3 Q. Have you consulted with any of these companies 4 you just listed, Edwards, Sorin, St. Jude, Abbott, 5 Cordis, or NDC with regard specifically to inferior 6 vena cava filters? 7 A. The only company of those that makes them is 8 Cordis, and I haven't talk to Cordis about vena cava 9 filters. 10 Q. Have you ever worked with any medical device 11 company with regard specifically to inferior vena cava 12 filters? 13 A. No. 14 Q. You have never been a full-time employee for a 15 private company, have you? 16 A. Full-time employee? No. 17 Q. And, in fact, your full-time employment has 18 always been in academia; is that correct? 19 A. Yes. Well, I had jobs -- full-time 20 employment, yes, yes. 21 Q. Do you hold any patents with regard to medical 22 devices? 23 A. No. 24 Q. Other than Cordis, have you ever consulted 25 with any company that does, to your knowledge,</p>

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<p>1 manufacture inferior vena cava filters?</p> <p>2 A. Well, if I did, I was unaware of it at the</p> <p>3 time.</p> <p>4 Q. You have never designed an inferior vena cava</p> <p>5 filter, have you?</p> <p>6 A. No. What are you saying, "inferior," or --</p> <p>7 what is the word before the "vena cava filter"?</p> <p>8 Q. Inferior vena cava.</p> <p>9 A. Inferior.</p> <p>10 Q. Right. IVC.</p> <p>11 A. No, I haven't.</p> <p>12 Q. Are you familiar with that term, "inferior</p> <p>13 vena cava"?</p> <p>14 A. Yes.</p> <p>15 Q. Have you ever designed any medical device?</p> <p>16 A. I have been part of a team that has designed</p> <p>17 those things. I have been involved in the assessment</p> <p>18 of their fracture susceptibility. I have given advice</p> <p>19 on the collection of data to support any</p> <p>20 life-prediction procedure. I have been part of</p> <p>21 life-prediction procedures, yes, so in that respect I</p> <p>22 have been part of the design.</p> <p>23 Q. Let me see if this is a fair characterization.</p> <p>24 Over the course of the years in some of your consulting</p> <p>25 work, you have been involved in the testing and sort of</p>	<p>1 A. NDC is of, course one, of the premiere</p> <p>2 manufacturers of Nitinol and Nitinol devices. I have</p> <p>3 put numerous students down there. I know those people</p> <p>4 very well, and we generally talk a lot about Nitinol</p> <p>5 and so forth. And I know the topic of these filters</p> <p>6 came up at some point, not recently, but we have talked</p> <p>7 about all sorts of devices made.</p> <p>8 Q. So you just referenced some conversations you</p> <p>9 may have had in the past. Let me ask you this way:</p> <p>10 Have any of your professional activities, whether it be</p> <p>11 teaching, publications, or consulting work, or research</p> <p>12 in the past, specifically dealt with inferior vena cava</p> <p>13 filters?</p> <p>14 A. "Specifically" means -- I mean, certainly the</p> <p>15 work I do on Nitinol will address the nature of a</p> <p>16 wire-wound -- a wire Nitinol device, but not</p> <p>17 specifically on filters. I haven't -- I haven't done a</p> <p>18 life prediction on filters or anything like that.</p> <p>19 Q. None of your past litigation cases involved</p> <p>20 inferior vena cava filters, did they?</p> <p>21 A. No, no.</p> <p>22 Q. Your curriculum vitae also indicates that you</p> <p>23 worked for -- in the late 1980s as a consultant for the</p> <p>24 Usci Division of Bard?</p> <p>25 A. Yes.</p>
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<p>1 analysis of prototype designs, but you have not</p> <p>2 actually designed a medical device yourself?</p> <p>3 A. No. That is a fair assessment.</p> <p>4 Q. Okay. You have never had occasion to address</p> <p>5 inferior vena cava filters in any of the classes that</p> <p>6 you have taught, have you?</p> <p>7 A. No. I may have made mention to various</p> <p>8 medical devices in the class, but nothing specific to</p> <p>9 those filters.</p> <p>10 Q. And your curriculum vitae, which has been</p> <p>11 marked as Exhibit No. 1 to this deposition, it contains</p> <p>12 a very long list of publications, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Do any of those publications deal specifically</p> <p>15 with inferior vena cava filters?</p> <p>16 A. No. Sorry, beg pardon.</p> <p>17 Q. Is it fair to say, then, that this particular</p> <p>18 litigation is your first experience specifically with</p> <p>19 inferior vena cava filters?</p> <p>20 A. What do you mean by -- I mean, I knew of these</p> <p>21 devices. I talked to NDC about some of these devices,</p> <p>22 but in terms of -- if you mean specifically focused</p> <p>23 solely on it, this is the first time, yes.</p> <p>24 Q. Tell me about conversations with NDC regarding</p> <p>25 inferior vena cava filters.</p>	<p>1 Q. Do you recall that?</p> <p>2 A. Yes. I don't recall what I exactly did there.</p> <p>3 I was working, but I did something with them. It</p> <p>4 wasn't very extensive. I tried to look up -- I</p> <p>5 couldn't find any details on that, but yes, I did.</p> <p>6 Q. That was from 1988 to 1990?</p> <p>7 A. What it says there. Yes.</p> <p>8 Q. Are you aware that Bard no longer owns the</p> <p>9 Usci Division?</p> <p>10 A. No. I was unaware of it.</p> <p>11 Q. One of several products that the Usci division</p> <p>12 marketed was a heart catheter that went under the trade</p> <p>13 name of "The Probe". Does that sound familiar to you?</p> <p>14 A. That is sort of vaguely familiar. I looked at</p> <p>15 my records the other day and nothing registered, I'm</p> <p>16 afraid, but there was something like that, yes. I</p> <p>17 don't recall very closely what it was. I only went</p> <p>18 there once or twice. It was a very short involvement.</p> <p>19 Q. Do you recall who you worked with there?</p> <p>20 A. No. I have no recollection.</p> <p>21 Q. Since 1990, have you done any work for C.R.</p> <p>22 Bard?</p> <p>23 A. No.</p> <p>24 Q. In the litigation consulting that you have</p> <p>25 done in the past, have any of those cases involved</p>

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<p>1 implantable medical devices?</p> <p>2 A. Yes.</p> <p>3 Q. What types of devices?</p> <p>4 A. Heart valves, primarily. I looked at aneurysm</p> <p>5 clips, and I have looked at orthopedic implants.</p> <p>6 Mainly, as I said, bone screws. None of these came to</p> <p>7 trial. Hip implants, and knee implants, but most of my</p> <p>8 work in the sort of devices that are nominally similar</p> <p>9 to what we are talking about today have been heart</p> <p>10 valves.</p> <p>11 Q. In the litigation cases that you have worked</p> <p>12 on that concerned heart valves, were you retained by</p> <p>13 individual plaintiffs or by a manufacturer?</p> <p>14 A. For heart valves, it was always by</p> <p>15 manufacturers.</p> <p>16 Q. Who were those manufacturers?</p> <p>17 A. Shiley.</p> <p>18 Q. I'm sorry, what?</p> <p>19 A. Shiley.</p> <p>20 Q. Okay.</p> <p>21 A. They were bought out by Pfizer, St. Jude</p> <p>22 Medical. And I did one case that involved -- I was</p> <p>23 never certain who I was working for, but it was</p> <p>24 Carbomedics and Baxter. I think they shared a lawyer,</p> <p>25 or shared...</p>	<p>1 I don't think there is anything else that is active at</p> <p>2 this point.</p> <p>3 Q. And what is your rate?</p> <p>4 A. I charge \$425 an hour.</p> <p>5 Q. Your report in this case indicates that you</p> <p>6 have testified in the past in front of the FDA?</p> <p>7 A. Yes.</p> <p>8 Q. When is the last time that you appeared in any</p> <p>9 proceeding involving the FDA?</p> <p>10 A. It was about two years, but I can't recall</p> <p>11 exactly. It was about two years ago. I went there on</p> <p>12 behalf of Edwards. It was about two years ago.</p> <p>13 Q. So you went there -- you were retained by a</p> <p>14 manufacturer to appear in front of the FDA?</p> <p>15 A. Yeah. I put "testified" in quotes, I think.</p> <p>16 It is quite frequent that during the process of the</p> <p>17 preliminary stages or submission of a PMA or an IDE to</p> <p>18 the FDA, that some sort of meeting is put forward, and</p> <p>19 maybe we are answering questions about -- that came up</p> <p>20 from some approval process. And I have gone there for</p> <p>21 various manufacturers over the years quite frequently</p> <p>22 and to talk to the FDA and to discuss some of these</p> <p>23 issues.</p> <p>24 Q. So these are not formal court or Congressional</p> <p>25 hearing-type proceedings, correct?</p>
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<p>1 Q. Aneurysm clips, was your litigation experience</p> <p>2 with those on behalf of the plaintiffs or</p> <p>3 manufacturers?</p> <p>4 A. I honestly can't recall. I think it was</p> <p>5 manufacturers. It was such a long time ago, that I</p> <p>6 can't recall.</p> <p>7 Q. What about with regard to orthopedic implants?</p> <p>8 A. Generally, that's been -- a number of lawyers</p> <p>9 in San Francisco tend to send me parts, so this would</p> <p>10 be for -- not the manufacturers. They sent me implants</p> <p>11 for me to look at and just give an opinion on how they</p> <p>12 failed, and none of these have gone beyond that. So I</p> <p>13 have just advised lawyers on how they may fail. I</p> <p>14 don't think I have ever worked for a manufacturer of an</p> <p>15 orthopedic implant.</p> <p>16 Q. So your understanding is, the lawyers that are</p> <p>17 contacting you with regard to orthopedic implants are</p> <p>18 lawyers that represent individual plaintiffs?</p> <p>19 A. Yes, indeed.</p> <p>20 Q. Now, other than the filter litigation that you</p> <p>21 are working on right now for Mr. Hartley and Mr. Davis,</p> <p>22 how many other litigation cases do you have that are</p> <p>23 active?</p> <p>24 A. I don't think any. I am about to get involved</p> <p>25 in one with St. Jude involving a heart-valve case, but</p>	<p>1 A. No, not at all.</p> <p>2 Q. And these are generally meetings between the</p> <p>3 manufacturer and the Food and Drug Administration to</p> <p>4 discuss some aspect of a submission or a planned</p> <p>5 submission?</p> <p>6 A. Yes, indeed.</p> <p>7 Q. And you have been retained by various</p> <p>8 manufacturers over the years to accompany them to these</p> <p>9 meetings and answer questions within your area of</p> <p>10 expertise?</p> <p>11 A. Yes, indeed.</p> <p>12 Q. Have you ever met with the FDA in any context</p> <p>13 in which you had not been retained by a medical device</p> <p>14 manufacturer?</p> <p>15 A. Well, I know of a lot of the people at the</p> <p>16 FDA, and I have met them at meetings, so that's where I</p> <p>17 might have seen them.</p> <p>18 Q. But that wasn't my question. Have you ever</p> <p>19 appeared before the FDA in a formal-type setting?</p> <p>20 A. No.</p> <p>21 Q. Other than the times in which you were</p> <p>22 retained by a medical device manufacturer to attend</p> <p>23 these meetings?</p> <p>24 A. I think that is accurate. I can't recall</p> <p>25 absolutely, but I think so.</p>



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<p>1 Q. We all know that sometimes, on occasion, 2 generally more with pharmaceutical products than 3 medical device products, the FDA will convene 4 scientific advisory panels -- 5 A. Yes, indeed. 6 Q. -- that do, in fact, entertain testimony? 7 A. Right. 8 Q. You have never testified in front of one of 9 those scientific advisory panels? 10 A. I haven't -- I did it once. It is -- again, I 11 was working for one of the heart-valve companies, and 12 they were appealing a ruling. And the FDA put forward 13 one of these -- what they call them now, panel -- I 14 think a panel review, I think it is called. And I 15 did -- I appeared before them. But those generally are 16 mostly medics, very few engineers. But I certainly 17 appeared before them. That was that long time ago, 18 sometime in the 90s. 19 Q. And that is the only time you recall appearing 20 before one of the panels or advisory committees of the 21 FDA? 22 THE REPORTER: Could you please slow down? 23 And the answer was... 24 THE DEPONENT: Most of the submissions that I 25 have been involved in, actually, have been successful</p>	<p>1 predicting the life of a stent. Maybe they are listed, 2 because they go all the way back. They probably are 3 listed. 4 Q. What is the most recent publication that you 5 have had with regard to Nitinol? 6 A. It is one that is in -- it is actually -- it 7 is just about to -- it has just been published. It is 8 going to come out in August, actually, but it is on the 9 Web. It is No. 623. Equivalent 10 Strain/Coffin-Manson Approach to Multiaxial Fatigue and 11 Life Prediction in Superelastic -- 12 THE REPORTER: I am sorry. Repeat that, 13 please. 14 THE DEPONENT: "Equivalent 15 Strain/Coffin-Manson Approach to Multiaxial Fatigue and 16 Life Prediction in Superelastic Nitinol Medical 17 Devices." 18 BY MR. NORTH 19 Q. Before that one, what was the most recent 20 publication you had specifically regarded to Nitinol? 21 Would that be No. 619, or 620, I guess? 22 A. 620 has just been accepted, so that is coming 23 out. 619, we're dealing with -- the paper's been 24 reviewed, and we have to answer some questions, and 25 then we will send that back. So that hasn't quite been</p>
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<p>1 and so that -- so that you wouldn't necessarily have 2 one of those panel reviews. They are fairly rare. So 3 for the case -- this was Medical Inc., I think, was the 4 heart valve company, and they wanted to appeal. And so 5 that was the one occasion. 6 BY MR. NORTH 7 Q. You have never had any dealings with the FDA 8 with regard to inferior vena cava filters, have you? 9 A. No, indeed. 10 Q. We already discussed the fact that none of 11 your previous publications specifically deal with 12 inferior vena cava filters. Do any of them 13 specifically deal with other implantable medical 14 devices? 15 A. Yes. Some do, yes. 16 Q. Such as what types of devices? 17 A. I worked -- I have written papers on heart 18 valves, many papers on heart valves. And I have 19 written papers on stent-like devices. Most of my focus 20 was to understand how they failed -- to predict their 21 life, their useful life in the body. So it is really 22 focusing on fatigue analysis. Some of these aren't 23 listed because the heart valve ones were done prior to 24 10 years ago. 25 I wrote one recently with the Cordis people on</p>	<p>1 accepted yet. 2 Q. Do either of those -- does 619 in any way deal 3 with your work in this particular case? 4 A. It is a general analysis of fatigue and 5 fracture in Nitinol. So it doesn't -- it is not 6 specific to any medical device per se. It is on the 7 topic of fatigue and fracture, and it is, again, 8 focused on medical devices, so wire-wound, wire-type 9 devices, but I can't recall -- I don't think there is 10 any mention of a filter in there. 11 Q. And when do you expect that to be published? 12 A. Probably later this year. I shouldn't be 13 presumptive. We have to -- it's been reviewed; it's 14 been nominally accepted. We have to respond to the 15 reviewers, which we are doing now, and it will probably 16 come out at the end of the year. 17 Q. Stents are generally manufactured out of 18 Nitinol tubing, aren't they? 19 A. They are laser-cut from tubing, yes. 20 Q. And that is a little bit different than 21 Nitinol wire, which is used in the filters, isn't it? 22 A. It's a different product form, yes. The heart 23 valves, on the other hand, often use wire type, like a 24 wire type these newer ones. 25 Q. Have any of your past publications dealt</p>

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<p>1 specifically with Nitinol wire as opposed to Nitinol 2 tubing? 3 A. I have looked at -- I have looked at various 4 different product forms of Nitinol, including wire, 5 tubing and plate, and tried to look at the difference 6 in their behavior. There is something called "texture" 7 in Nitinol, which is how the grains form, and these can 8 change from product form. So in that regard, I have 9 looked at it. 10 Q. Are most of your Nitinol-related publications 11 dealing with Nitinol tubing? 12 A. No. They looked at different -- I mean, a lot 13 of it recently has been based on medical devices, so it 14 is general to Nitinol. But I have looked at plate and 15 I have looked at tubing and various different product 16 forms. 17 Q. Can you estimate for me what percentage of 18 your income is derived from litigation consulting? 19 A. Pretty small. Ten percent. And by the way, 20 litigation, I mean, I am referring to all sorts of 21 consulting. Some of it may not be litigation-related, 22 but, you know, consulting -- I work for certain 23 companies that call me in to ask about certain things, 24 nothing to do with legal cases. But my consulting 25 income is typically about 10 percent of what I earn,</p>	<p>1 often shown that, and I have, you know, given my 2 opinion on occasion. But -- so that is my involvement, 3 certainly. I mean, with some of the heart valves, 4 where they were inserting certain disks into a metals 5 occluder, I certainly gave advice on how they should or 6 shouldn't do that, which affected that manufacturing 7 process. 8 Q. Have you ever been involved in the actual 9 writing specifications for a manufacturing process for 10 a medical device? 11 A. I have written -- I have written reports which 12 undoubtedly have been used to develop some of those 13 specifications. But, no, I haven't actually written 14 them myself. A consultant wouldn't necessarily do 15 that. 16 Q. You are not a medical doctor, correct? 17 A. I am not a medical doctor. 18 Q. You are not an expert in anatomy, are you? 19 A. I am not an expert in anatomy. 20 Q. And you are not an expert on physiology? 21 A. I am not an expert in physiology. I work on 22 bone, and I work on teeth. That is my involvement. 23 Q. In the heart-valve litigation, are there any 24 attorneys with which you work primarily? 25 A. No, I can't recall. I mean, when I was</p>
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<p>1 probably a little bit less. 2 Q. Looking at your curriculum vitae, beginning on 3 Page 2 and carrying over to Page 3, there is a list of 4 what you call "activities." 5 A. Yes. 6 Q. And those involve various journals in which 7 you have been involved, symposia and conferences and 8 things of that nature that you have presided over, 9 correct? 10 A. Yes, indeed. 11 Q. Do any of those activities specifically -- or 12 did they specifically focus on Nitinol? 13 A. Well, as an editor -- on an editorial board of 14 the journal, certainly the issue of Nitinol comes up, 15 but most of them are in general -- in the general 16 materials field with focus on fatigue and fracture. 17 Q. None of those activities specifically dealt 18 with inferior vena cava filters, to your knowledge, did 19 they? 20 A. No, no. None. Not specifically, anyway. 21 Q. Have you ever been involved in consulting with 22 a manufacturer about the actual manufacturing process 23 or assembly-line process for creation of a medical 24 device? 25 A. Well, when I visited these companies, I am</p>	<p>1 working with Shiley, it was mainly during the period 2 when their valves started to fail. So I was not 3 involved in a lot of the legal aspects; I was involved 4 in trying to find out why they failed and looking at 5 the newer valves. For St. Jude, I did do a number of 6 litigation, and I have no recollection of who the 7 lawyers were. So I -- that is all -- I can't tell you 8 anything else. 9 Q. Have you consulted with lawyers from Los 10 Angeles on behalf of St. Jude? 11 A. I honestly can't recall. I have a conference 12 call with one tomorrow, but I am not quite sure where 13 she is from. 14 Q. Have you -- has your testimony ever been 15 excluded by a judge, to your knowledge? 16 A. I think there was a case a long time ago where 17 I worked for -- a lawyer in San Francisco had a knee 18 implant. And -- who never paid me, by the way -- and 19 he went bankrupt afterwards, but I think there was some 20 issue there about -- that my testimony was excluded 21 because they said I wasn't a manufacturing expert. I 22 think that's what it was about. 23 Q. Do you recall whether that was in state or 24 Federal court? 25 A. No clue. No idea.</p>

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<p>1 Q. Do you recall how long ago that was?</p> <p>2 A. Fifteen years, maybe.</p> <p>3 Q. Do you recall -- well, you would have been</p> <p>4 retained on behalf of an individual plaintiff in that</p> <p>5 case? Is that correct?</p> <p>6 A. Yes, indeed.</p> <p>7 Q. Do you recall who the manufacturer was?</p> <p>8 A. No. I don't recall.</p> <p>9 Q. But your recollection is that was right here</p> <p>10 in San Francisco?</p> <p>11 A. It was in San Francisco, yes.</p> <p>12 Q. We have talked some about your litigation</p> <p>13 consulting work with regard to medical devices. What</p> <p>14 other sorts of products have you done litigation</p> <p>15 consulting about?</p> <p>16 A. Aerospace. I do a lot of work on -- I was</p> <p>17 part of the Sioux City, Iowa DC-10 crash; I was</p> <p>18 involved in that. I worked on helicopter crashes. I</p> <p>19 have done exploding propane cylinders. Anything that</p> <p>20 breaks or particularly fatigues is something that I</p> <p>21 often get called into. I haven't done as many lately;</p> <p>22 I haven't had time, being head of department. I did a</p> <p>23 couple of automobile cases, pretty small. I think that</p> <p>24 is about it.</p> <p>25 Q. Have you -- who were you retained on behalf of</p>	<p>1 A. A large proportion. I may have found an odd</p> <p>2 publication in the literature. But I would think, yes,</p> <p>3 most of it all came from Dean Hartley.</p> <p>4 Q. So if we have a list of materials that you</p> <p>5 have relied upon and reviewed as a part of your work in</p> <p>6 this case, it is fair to say that virtually all of that</p> <p>7 material would have come from the Plaintiff's lawyers,</p> <p>8 with the possible exception of a handful of additional</p> <p>9 articles?</p> <p>10 A. Yes. I think that is a fair comment.</p> <p>11 Q. You were provided with a number of depositions</p> <p>12 in this case, weren't you?</p> <p>13 A. Way too many, but, yes.</p> <p>14 Q. Did you read those depositions?</p> <p>15 A. I have read most of them. I haven't read --</p> <p>16 actually, there is two or three that I have yet to</p> <p>17 read, but I have read most of them.</p> <p>18 Q. Did you make any notes concerning those</p> <p>19 depositions?</p> <p>20 A. Yeah, I have made -- scribbled noted, yes.</p> <p>21 Q. Did you bring those notes with you?</p> <p>22 A. They are on the copy of the deposition.</p> <p>23 Q. Did you bring the copies of the deposition?</p> <p>24 A. No, I didn't, because it was too big. It is a</p> <p>25 massive file. I brought everything else, but not that.</p>
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<p>1 in the Sioux City United Airlines crash?</p> <p>2 A. Sidley &amp; Austin. They are out of Chicago. I</p> <p>3 was working for General Electric. They were working</p> <p>4 for General Electric.</p> <p>5 Q. Have you ever worked with Dean Hartley before?</p> <p>6 A. No.</p> <p>7 Q. Have you ever worked with his colleague, Jack</p> <p>8 Davis?</p> <p>9 A. No.</p> <p>10 Q. Do you know how they got to you in this</p> <p>11 particular case, how they located you?</p> <p>12 A. No.</p> <p>13 Q. Do you know who recommended you to them?</p> <p>14 A. No.</p> <p>15 Q. You were given a number of depositions and</p> <p>16 documents to review in this case; is that correct?</p> <p>17 A. Indeed.</p> <p>18 Q. And who provided those to you?</p> <p>19 A. It was sent to me by either Dean or Jack; I am</p> <p>20 not sure who, but it was...</p> <p>21 Q. We were previously furnished a list of the</p> <p>22 materials that you were provided, or that you had</p> <p>23 reviewed as a part of your work in this case. Did all</p> <p>24 of the materials you reviewed come from either</p> <p>25 Mr. Davis or Mr. Hartley?</p>	<p>1 Q. Okay. Let me ask you, did you read the</p> <p>2 deposition of Robert Carr?</p> <p>3 A. Yes.</p> <p>4 Q. What is it you just pulled out of your --</p> <p>5 A. Just a list of the depositions that were sent.</p> <p>6 And that just indicates who these people are.</p> <p>7 Q. If they have checkmarks by them --</p> <p>8 A. Then I have read them.</p> <p>9 Q. If we could mark this as Exhibit 2 to the</p> <p>10 deposition.</p> <p>11 A. You are not going to take that away from me.</p> <p>12 Q. What we'll do is we will make a copy of it at</p> <p>13 the end of the deposition.</p> <p>14 (Whereupon Defendants' Exhibit No.</p> <p>15 2 was marked for identification.)</p> <p>16 BY MR. NORTH</p> <p>17 Q. Doctor, how did you determine which</p> <p>18 depositions you would read and which ones you would not</p> <p>19 read?</p> <p>20 A. Their order in the book.</p> <p>21 Q. So you read a number of them, and then you</p> <p>22 just quit reading them?</p> <p>23 A. I didn't have time to finish them. I have got</p> <p>24 through all but two.</p> <p>25 Q. Well, according to this chart -- well, let me</p>

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DEPOSITION OF ROBERT O. RITCHIE, PH.D.

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<p>1 be sure I am correct. On the chart that is Exhibit 2, 2 if the deposition does not have a check-mark on the 3 left-hand side, that means you have not read it, 4 correct? 5 A. That is not quite true. I am in the middle of 6 Kaufmann. So, yes. 7 Q. Okay. So you are in the middle of reading 8 Dr. Kaufmann, but you have not completed it? 9 A. I have got a few pages to finish. 10 Q. You have not read the deposition of John 11 McDermott? 12 A. Not yet. 13 Q. You have not read the deposition of Sherry 14 Allen? 15 A. Not yet. 16 Q. You have not read the deposition of Janet 17 Hudnall? 18 A. Not yet. 19 Q. As I understand it, you were not furnished the 20 deposition of Tony Venbrux? 21 A. No. 22 Q. And you were not furnished the deposition of 23 Dr. William Stavropoulos? 24 A. No. 25 Q. And you were not furnished the deposition of</p>	<p>1 A. Peripherally, yes. 2 Q. Was he involved at all in referring these 3 cases to you? 4 A. It is possible. I don't know exactly, but it 5 is possible, because he actually -- after he left me 6 and went to work for -- I think it was Cordis at that 7 time, he did a study on these -- the failure of these 8 filters. And I think that was before I was retained. 9 So I don't know quite what his involvement was with 10 Dean Hartley and Jack Davis, but I certainly talked to 11 him about it -- peripherally about these failures at 12 that time. 13 Q. But you don't recall any specific conversation 14 where he indicated to you that he had referred you -- 15 referred Mr. Hartley and Mr. Davis to you? 16 A. Maybe he did. I can't recall. Maybe he did. 17 I mean, it seems -- it is possible he could have done 18 that, but I don't recall exactly. 19 Q. You mentioned that you -- advised that you had 20 never worked before with Mr. Davis or Mr. Hartley. 21 Have you ever worked with Mr. Tim Casey out of Phoenix? 22 A. I don't think so. 23 Q. Have you ever worked with a New York City law 24 firm Weitz &amp; Luxenberg? 25 A. I don't think so.</p>
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<p>1 Scott Trerotola? 2 A. No. 3 Q. You were provided with a copy of the Nicholson 4 article -- the York study regarding the recovery filter 5 and G2 filter? 6 A. Yes. 7 Q. But you were not provided a copy of Dr. 8 William Nicholson's deposition regarding that study, 9 were you? 10 A. No. 11 Q. And you were not provided a copy of the 12 deposition of the deposition of Dr. Nicholson's 13 research coordinator, Barbara Delio Cox, were you? 14 A. No. 15 Q. And you were not provided with a copy of the 16 deposition of Avuit Mukherjee, were you? 17 A. No. 18 Q. When were you first retained in this case? 19 A. In 2009, I believe. I am not sure of the 20 exact date. 21 Q. You are familiar with Mr. Scott Robertson, Dr. 22 Scott Robertson? 23 A. He was my student and postdoc. 24 Q. Have you had discussions with him concerning 25 this litigation?</p>	<p>1 Q. So you were first, as you said, retained in 2 this case in 2009. 3 A. I believe so, yes. 4 Q. And you were -- were you provided some 5 materials at that time? 6 A. I was -- in 2009, I was certainly given some 7 filters to look at, because I make a note in my files 8 about when I received them, and a lot of filters came 9 to me in 2009. 10 Q. Did you bring your log of when you received 11 various information today? 12 A. I don't really have such a log. But I mean, 13 in my computer when I list -- I list the -- actually, I 14 have that if you are interested. Yeah, I have a CD 15 of -- well, I sent it to you. You have the CD of my -- 16 all of the pictures that I took of the valves, and each 17 of the headings for each filter actually lists the date 18 of receipt. I can fire up my computer and give them to 19 you if you want. 20 Q. That is okay. So the pictures of the filters 21 that you previously furnished to us will bear the date 22 that you received the filters? 23 A. I believe so. The heading -- of the file 24 heading which, you know, for each particular filter, be 25 it gray or what have you, should have a parenthesis</p>

12 (Pages 45 to 48)



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<p>1 after that says "received" and the date. On most of  2 them -- one I didn't get the exact date. If you don't  3 have it, I can certainly furnish it to you.  4 Q. Can you tell me how much money you have billed  5 Mr. Hartley and Mr. Davis for your work thus far in  6 this case?  7 A. Not offhand, but I have a list of my bills if  8 you want them.  9 Q. Do you have them here?  10 A. I have them on the CD, if that is okay.  11 Q. Okay. And I would assume that you have had a  12 number of graduate assistants assisting you in this  13 matter?  14 A. I have had two postdocs, actually, who have  15 helped me with this.  16 Q. And do you charge for their time?  17 A. I pay them from what I earn. You know, I pay  18 them basically for their work.  19 Q. But do you separately bill Mr. Hartley and  20 Mr. Davis for their time at some sort of hourly rate?  21 A. I can't remember what I did there. But I  22 think -- I generally include it in whatever -- I mean,  23 I sit with them on the microscope, and I pay them out  24 of what I earn.  25 I don't think there is any separate billings.</p>	<p>1 first by Mr. Davis and Mr. Hartley, or was it Professor  2 McMeeking?  3 A. I was approached first.  4 Q. And then did you recommend that Mr.  5 McMeeking -- Professor McMeeking also be brought on  6 board the team?  7 A. Yes, I did.  8 Q. Then was it Professor McMeeking that suggested  9 that Professor Begley help him?  10 A. Yeah. When I suggested Professor McMeeking,  11 Professor Begley wasn't even at Santa Barbara at that  12 point. Begley's involvement would have been due to a  13 recommendation from Professor McMeeking.  14 Q. Now, how do you envision the different roles  15 that you and Professor McMeeking play in the analysis  16 of this litigation?  17 A. Well, in all of the times we have been  18 involved in cases together, I mean, the issues have  19 often been associated with fracture and fatigue. And  20 the two primary factors involved there are the material  21 and the stresses that it sees. And we both consider  22 ourselves to be fairly cognizant of both aspects,  23 although my particular forte is looking at the failure  24 processes, and his particular forte is looking at the  25 computation of the stresses.</p>
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<p>1 There may have been a separate billing for microscope  2 time on one occasion, but largely it is just billed --  3 I pay them out of what I earn.  4 Q. Have you spoken with any of the individual  5 plaintiffs in this litigation?  6 A. No.  7 Q. Have you spoken with any of the witnesses that  8 have been deposed?  9 A. No.  10 Q. Have you spoken with any of the Plaintiffs'  11 other expert witnesses?  12 A. Well, I have spoken with Professors McMeeking  13 and Begley.  14 Q. Have you worked with Professors McMeeking and  15 Begley in the past?  16 A. I have worked with Professor McMeeking for  17 many years. We did a lot of the Shiley cases together.  18 We did some Jude cases together. We were working with  19 Sorin together. I work with Begley -- I have written a  20 paper with him recently, but this is the first  21 consulting job I have worked with Begley.  22 Q. So in the past, you have done a fair amount of  23 litigation consulting with Professor McMeeking?  24 A. Yes, indeed.  25 Q. In this particular case, were you approached</p>	<p>1 So I am a strong believer that in anything  2 that fails, perhaps the most important thing is to know  3 what the stresses are. So I have always recommended  4 that who I consider the most competent stress analysis  5 on the planet is involved. And that's why I got  6 Professor McMeeking involved.  7 Q. I am hoping not to butcher this, but for a lay  8 perspective, I would like to try to characterize what I  9 think I understood you to say. Your -- from a lay  10 perspective, your role, as you see it, was to determine  11 why these failures occurred, what the process was that  12 caused these failures?  13 A. Yes.  14 Q. And in turn, Dr. McMeeking's role was to  15 compute or try to quantify the stresses that led to the  16 failures you identified?  17 A. Yeah. But, I mean -- absolutely right. But  18 of course those two aspects merge, of course. But  19 yeah, his, his -- he is a numerical stress analyst, and  20 I am a material scientist, so I think that is a fair  21 assessment.  22 Q. Have you had any meetings with Dr. McMeeking  23 and Dr. Begley regarding this matter?  24 A. We certainly talked on the phone, but no  25 specific meetings.</p>

13 (Pages 49 to 52)



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<p>1 Q. On how many occasions have you talked on the 2 phone with him? 3 A. Two or three times. 4 Q. Did you review their report before it was 5 finalized? 6 A. No. 7 Q. Did they review your report before it was 8 finalized? 9 A. Possibly. Yeah, I think I sent them a copy of 10 my report. 11 Q. Did they make any recommendations or edits for 12 the report? 13 A. No. 14 Q. But you did not look at their report until it 15 was finished? 16 A. I didn't see it until it was submitted, yes. 17 Q. You have since seen it? 18 A. Oh, yes. 19 Q. Is there anything in that report with which 20 you disagree? 21 A. No. I think it is a very good report. 22 Q. Have you ever talked to an -- as part of your 23 work in this case, have you ever talked with an 24 interventional radiologist concerning inferior vena 25 cava filters?</p>	<p>1 heart-valve case. But I don't think it was ever 2 published for some reason. 3 Q. In your report, you list on Page 17 a number 4 of references; is that correct? 5 A. Yes. 6 Q. Were the majority of those references provided 7 to you by Mr. Hartley and Mr. Davis? 8 A. Well, certainly from ten onwards. Eleven was 9 definitely provided by them. I honestly can't recall 10 exactly. They certainly -- certainly numbers 10 and 11 12, 13 and 14 were not provided. And I can't remember 12 in each individual case whether I found that by Google 13 Scholar or whether it was sent to me. 14 Q. The first nine articles all have to do with 15 inferior vena cava filters? 16 A. Right. 17 Q. Were those all sent to you by Mr. Davis and 18 Mr. Hartley? 19 A. I don't think the individual papers were sent 20 to me. As I said, I think they sent me a list at some 21 point. I can't honestly recall, but I certainly looked 22 around to see what was out there. I use Google Scholar 23 a lot. I can find some of these papers, so some of 24 them I may have found myself. I honestly can't 25 remember.</p>
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<p>1 A. No. 2 Q. In your discussions with Professors McMeeking 3 and Begley, did you all specifically discuss 4 electropolishing? 5 A. Not really. I mean, the topic may have been 6 mentioned, but that is not something that they would 7 be -- I can't say that. We peripherally talked about 8 it, but as it may address the stress states, yes. 9 Q. Did you have any specific discussions with him 10 about chamfers? 11 A. Yes. We talked about that, certainly. 12 Q. Have you had any discussions in this 13 litigation with Dr. Joseph Dyro? 14 A. No. 15 Q. Have you had any discussions with Dr. Jeffrey 16 Hull? 17 A. No. 18 Q. Have you had any discussions with any of the 19 Plaintiffs' other experts, other than Drs. McMeeking 20 and Begley? 21 A. No. 22 Q. Have you published any papers in the past with 23 Dr. McMeeking? 24 A. I don't think so. We had one paper, actually, 25 we were going to publish with Baxter about a</p>	<p>1 Q. You were not provided, as I understand it, 2 with the Society of Interventional Radiologists' 3 quality improvement guidelines for filters, were you? 4 A. I don't think so. 5 Q. All of the specifications and operating 6 procedures for the manufacture of the recovery filter 7 were provided to you by Mr. Hartley and Mr. Davis, 8 correct? 9 A. Does the "all" refer to all of the docs or the 10 papers that I have received? 11 THE REPORTER: All of what, sir? 12 THE DEPONENT: What do you mean by "all?" I 13 mean, all of the ones that exist or that were sent to 14 me? 15 BY MR. NORTH 16 Q. I don't think you heard my question. I said, 17 "all of the specifications or operating procedures for 18 the recovery filter." 19 A. Yes. But my question is, are you referring to 20 all of the ones that exist or all of the papers that I 21 received? Everything I received on operating 22 instructions, I received from Mr. Hartley or Jack 23 Davis. 24 Q. Right. Okay. 25 A. But it may not pertain to all of the ones that</p>

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<p>1 exist. I can't speak to that.</p> <p>2 Q. And you simply relied on Mr. Davis and</p> <p>3 Mr. Hartley to determine which ones they were to</p> <p>4 provide to you?</p> <p>5 A. If there were more than they sent me, yes.</p> <p>6 Q. Were you provided the European standard or the</p> <p>7 FDA guideline for the development of inferior vena cava</p> <p>8 filters?</p> <p>9 A. No.</p> <p>10 Q. You were furnished some reports obtained by</p> <p>11 Bard from a company called Altran --</p> <p>12 A. Yes.</p> <p>13 Q. -- regarding the evaluation of some fractured</p> <p>14 filters in the 2003, 2004 time frame?</p> <p>15 A. Yes.</p> <p>16 Q. Did you review those reports?</p> <p>17 A. Yes.</p> <p>18 Q. As I understand it, you were not provided</p> <p>19 Bard's communications back and forth with the FDA</p> <p>20 regarding the testing of this device, were you?</p> <p>21 A. I was provided with -- as it pertains to what</p> <p>22 is in the notes for Kay Fullo's deposition, the 510K</p> <p>23 application is in there, and there is a lot of</p> <p>24 subsequent discussion both within Bard and with the FDA</p> <p>25 about that particular submission. So I have certainly</p>	<p>1 Mr. Davis?</p> <p>2 A. One of the early ones, I have forgotten which</p> <p>3 one it was, was done down at NDC. I mean, I asked --</p> <p>4 that is right. I think somebody who worked for NDC</p> <p>5 looked at one of the earliest valves -- one of the</p> <p>6 earliest filters, rather, and then sent me a set of</p> <p>7 photographs.</p> <p>8 Q. Had somebody from NDC been contacted by</p> <p>9 Mr. Davis and Mr. Hartley regarding this project before</p> <p>10 you were brought in?</p> <p>11 A. That is quite possible, now that I think about</p> <p>12 it. I can't recall why we sent it down there, but yes.</p> <p>13 That may be where the involvement of Scott Robertson</p> <p>14 came from.</p> <p>15 Q. Was he at NDC at that time period?</p> <p>16 A. Yes. It was part of Cordis at that time</p> <p>17 period.</p> <p>18 Q. Did Mr. Launey or Mr. Gludovatz or both of</p> <p>19 them assist in drafting the report?</p> <p>20 A. Not at all.</p> <p>21 Q. On Page 4 of your report, you discuss your</p> <p>22 methodology for examining these filters?</p> <p>23 A. Yes.</p> <p>24 Q. Generally, what was the condition of the</p> <p>25 filters? And I am talking here about the explanted</p>
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<p>1 seen that.</p> <p>2 Q. Did you see the actual documents? Were they</p> <p>3 attached to Kay Fullo's deposition, or was it just her</p> <p>4 discussion about them?</p> <p>5 A. No. The actual documents were there, and</p> <p>6 there is, of course, her discussion, too.</p> <p>7 Q. Do you know the materials expert that has been</p> <p>8 designated by C.R. Bard in this case?</p> <p>9 A. This -- is this the woman who wrote the report</p> <p>10 from Anamet?</p> <p>11 Q. Yes. Dr. Fasching.</p> <p>12 A. I don't know her that well.</p> <p>13 Q. What were the names of the two assistants that</p> <p>14 worked with you on this project?</p> <p>15 A. My first postdoc was called Max Launey, M-a-x,</p> <p>16 L-a-u-n-e-y.</p> <p>17 Q. L-a-u-n-e-y?</p> <p>18 A. Yes. And my current postdoc has an</p> <p>19 Eastern-European name that I cannot either pronounce or</p> <p>20 spell, so give me a second. His name is Bernd,</p> <p>21 B-e-r-n-d, and his surname is G-l-u-d-o-v-a-t-z.</p> <p>22 Q. Gludovatz?</p> <p>23 A. Gludovatz, right.</p> <p>24 Q. Did Mr. Launey and Mr. Gludovatz examine all</p> <p>25 of the filters that you received from Mr. Hartley and</p>	<p>1 filters, not the exemplar filters, but the ones that</p> <p>2 had been removed from people's bodies. What was their</p> <p>3 condition generally at the time you received them?</p> <p>4 A. Some of them had a little bit of tissue on</p> <p>5 them and so forth. We can't handle that; we are not</p> <p>6 allowed to handle anything like that. So at the time I</p> <p>7 requested from Mr. Hartley, and presumably through you,</p> <p>8 what I could do to clean them before I could put them</p> <p>9 in the microscope.</p> <p>10 Q. And so you subjected these filters that had</p> <p>11 been returned to you to some sort of sterilization</p> <p>12 process?</p> <p>13 A. Yeah. We have to just -- exactly what it is.</p> <p>14 This is also important when you put it in a scanning</p> <p>15 electron microscope and you need to get rid of dust --</p> <p>16 THE REPORTER: Say that again.</p> <p>17 THE DEPONENT: A scanning electron microscope</p> <p>18 particles and you need to get rid of dust particles and</p> <p>19 this sort of thing that charge up in the microscope.</p> <p>20 So they need to be -- we obviously clean them as well,</p> <p>21 but the main thing is the sterilization; we can't</p> <p>22 handle that.</p> <p>23 BY MR. NORTH</p> <p>24 Q. Well, when you would receive the filters, how</p> <p>25 did you handle them? Do you use tweezers?</p>

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<p>1 A. We use tweezers and gloves, yes.</p> <p>2 Q. And so you would have used tweezers on these</p> <p>3 filters before you actually examine them, and then --</p> <p>4 will you let me finish my -- I'm sorry, if I don't</p> <p>5 finish my question before you answer, it she can't do</p> <p>6 the transcript.</p> <p>7 A. I beg your pardon.</p> <p>8 Q. Did you use the tweezers to handle the filters</p> <p>9 as a part of the sterilization process?</p> <p>10 A. You know, I can't remember exactly, but we --</p> <p>11 whether we used tweezers or not. We wouldn't use metal</p> <p>12 tweezers; that could possibly damage the filters. So</p> <p>13 we would certainly use gloves and they would be put</p> <p>14 into a -- you know, a beaker and soaked in this</p> <p>15 solution. That's how we did it. So the tweezers would</p> <p>16 not -- we have some plastic tweezers; I don't think</p> <p>17 they were used here. I think we just used hands and</p> <p>18 gloved hands.</p> <p>19 Q. It sounds like in the way you describe that,</p> <p>20 that it would have been your assistants and not you --</p> <p>21 let me finish my question, please. This transcript is</p> <p>22 going to be a mess if we don't do it. It sounds to me</p> <p>23 in the way you described that, that it was your</p> <p>24 assistants that would have sterilized it, not you?</p> <p>25 A. Absolutely.</p>	<p>1 meaning from the point of view of evidence. So we are</p> <p>2 very, very careful of this.</p> <p>3 Q. At my request, you subsequently shipped these</p> <p>4 filters to me, correct?</p> <p>5 A. Indeed, yes.</p> <p>6 Q. Two of the filters we received had a number of</p> <p>7 small prongs clipped off of them.</p> <p>8 A. Yes, indeed.</p> <p>9 Q. Do you know how that occurred?</p> <p>10 A. No. I presume that was done during explant or</p> <p>11 something, but I certainly didn't do that. One of them</p> <p>12 had, I think, four legs cut off or the feet cut off.</p> <p>13 That would -- we would not have done that, of course.</p> <p>14 Q. So is it your testimony that they arrived in</p> <p>15 your possession from Mr. Hartley and Mr. Davis in that</p> <p>16 condition?</p> <p>17 A. One hundred percent, absolutely.</p> <p>18 MR. NORTH: With the understanding that you</p> <p>19 obviously can keep this book, I would like to just mark</p> <p>20 his report as Exhibit 3, and then we'll substitute a</p> <p>21 non-bound copy of that.</p> <p>22 Okay. I have 20 pounds of exhibits and don't</p> <p>23 have his C.V.</p> <p>24 (Whereupon Defendants' Exhibit No.</p> <p>25 3 was marked for identification.)</p>
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<p>1 Q. So you didn't sterilize any of these filters?</p> <p>2 A. No. They sterilized it for me.</p> <p>3 Q. Did you observe them sterilizing any of these</p> <p>4 filters?</p> <p>5 A. Yes.</p> <p>6 Q. Did you observe them sterilizing all of these</p> <p>7 filters?</p> <p>8 A. No. I gave instructions how it should be</p> <p>9 done, certainly. I mean, one of the problems here is</p> <p>10 that you have to be very careful that you don't damage</p> <p>11 anything in the process of cleaning them, but virtually</p> <p>12 every device, every failure that is looked at in the</p> <p>13 scanning microscope, which is generally used in</p> <p>14 99 percent of all of these cases, you have to clean</p> <p>15 them. So this is a process that we are well used to</p> <p>16 and...</p> <p>17 Q. And just so I understand the rhythm, the</p> <p>18 sterilization occurs before they are placed under the</p> <p>19 microscope?</p> <p>20 A. Of course. Yes.</p> <p>21 Q. Did you understand that you were not to</p> <p>22 perform any destructive testing on the filters?</p> <p>23 A. Absolutely. Absolutely. That's why I sought</p> <p>24 advice over the sterilization. Sometimes people seem</p> <p>25 to think that tissue on those things could have some</p>	<p>1 BY MR. NORTH</p> <p>2 Q. So we have marked as Exhibit 3 your report in</p> <p>3 this case, correct?</p> <p>4 A. Well, there are several versions, so I don't</p> <p>5 know which one -- that is the Newton one, right?</p> <p>6 Q. Okay, then that is the main report, correct,</p> <p>7 the Newton report?</p> <p>8 A. They are all the same. They just -- the way</p> <p>9 the report is written, there is an appendix which</p> <p>10 describes the individual filter failures which are</p> <p>11 pertinent to that particular case.</p> <p>12 Q. But the main report is the same for every</p> <p>13 case?</p> <p>14 A. The main report is the same for every case.</p> <p>15 Q. And what we have marked is the main report,</p> <p>16 then with the filter, specific discussion for the</p> <p>17 Newton case, correct?</p> <p>18 A. You have, indeed. Yes.</p> <p>19 Q. Did Mr. Launey and Mr. Gludovatz examine these</p> <p>20 filters under the scanning electron microscope?</p> <p>21 A. They operated the microscope, yes.</p> <p>22 Q. Did you look at each and every filter, or did</p> <p>23 they look at some and report to you what they found?</p> <p>24 A. I looked at all of them.</p> <p>25 Q. What do you mean when you say, "They operated</p>

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<p>1 the microscope?"</p> <p>2 A. They turned the knobs. This is a complicated</p> <p>3 tool. You have to pump the thing down and vacuum and</p> <p>4 then you -- so this is something that they do most of</p> <p>5 the time at the lab, so they operate it for me.</p> <p>6 Q. Did they provide you any written notes or</p> <p>7 report of their observations in the microscope?</p> <p>8 A. I got little notes saying, "Three or four legs</p> <p>9 broke" just to supplement -- a couple of sentences to</p> <p>10 supplement the images that I got. Most important was</p> <p>11 the images, which was a record of what we looked at</p> <p>12 when we looked in the microscope. I sent those to you.</p> <p>13 Q. Who made these one or two sentences of notes,</p> <p>14 you or Mr. Launey or Mr. Gludovatz?</p> <p>15 A. They would have been written after the fact</p> <p>16 several -- four legs broke, three legs broke, something</p> <p>17 like that.</p> <p>18 Q. Did you personally choose the magnification</p> <p>19 level for the scanning electronic microscope?</p> <p>20 A. That is a difficult -- I asked them to look at</p> <p>21 the surface, to look at the fracture surfaces, so that</p> <p>22 would be something that is done as you examine. So a</p> <p>23 priori you wouldn't fix the microscope. You put it at</p> <p>24 a magnification that you can see what you want to see.</p> <p>25 Q. You told me earlier that you drafted the</p>	<p>1 Q. And he has worked over the years for Cordis,</p> <p>2 correct, companies affiliated with Cordis?</p> <p>3 A. NDC and Cordis were the same company, and then</p> <p>4 they separated. Now he works for NDC. He actually, I</p> <p>5 think, formed his own company within NDC, making</p> <p>6 filters, I believe, which are recently sold. I don't</p> <p>7 know the full story about that.</p> <p>8 Q. Are you aware of the fact that he has</p> <p>9 attempted to market a filter?</p> <p>10 A. Yes. I think --</p> <p>11 Q. Let me finish -- that he has attempted to</p> <p>12 market filter products to Bard?</p> <p>13 A. No. I was not aware of that.</p> <p>14 Q. Are you aware of the fact that he is generally</p> <p>15 trying to market various filter designs?</p> <p>16 A. My understanding was that he had formulated</p> <p>17 his own company within NDC making a filter, and that he</p> <p>18 recently sold that. And that is my -- that is all I</p> <p>19 know about it. I don't know any further than that. I</p> <p>20 don't know what kind of filter, or where it is made or</p> <p>21 anything.</p> <p>22 Q. When is the last time you talked to</p> <p>23 Dr. Robertson?</p> <p>24 A. A week or so, two weeks ago. We have this</p> <p>25 paper coming out, so we had to talk about that.</p>
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<p>1 report that's been marked as Exhibit 3?</p> <p>2 A. I drafted it and I wrote it.</p> <p>3 Q. Did Mr. Launey or Mr. Gludovatz provide</p> <p>4 revisions for the report?</p> <p>5 A. No.</p> <p>6 Q. Now I believe you have said even though you</p> <p>7 may have shared it with Mr. McMeeking, he did not</p> <p>8 provide any revisions to the report?</p> <p>9 A. No.</p> <p>10 Q. Nor did Dr. Begley?</p> <p>11 A. No.</p> <p>12 Q. What about Mr. Hartley and Mr. Davis?</p> <p>13 A. They called me up and said there is a bunch of</p> <p>14 typos, and they went through a bunch of typos with me.</p> <p>15 Q. For any reason, did you pull out any expert</p> <p>16 reports that you had done in other litigation to assist</p> <p>17 you in preparing this report?</p> <p>18 A. No.</p> <p>19 Q. Now, we were talking earlier about Scott</p> <p>20 Robertson. My understanding is he was a Ph.D. student</p> <p>21 under your guidance here, correct?</p> <p>22 A. He was my Ph.D. student, yes.</p> <p>23 Q. And you have co-authored a number of articles</p> <p>24 with Dr. Robertson?</p> <p>25 A. Indeed.</p>	<p>1 Q. When is the last time you talked to him</p> <p>2 specifically about this litigation?</p> <p>3 A. I don't think we have talked specifically</p> <p>4 about this litigation. I can't recall. We talk about</p> <p>5 Nitinol a lot and the papers we have written. I don't</p> <p>6 think -- this litigation may have come up peripherally.</p> <p>7 I don't know, but nothing -- nothing specific.</p> <p>8 Q. Do you know one way or the other whether the</p> <p>9 filter or filters that his company has designed and</p> <p>10 attempted to market are electropolished?</p> <p>11 A. I would imagine they are, but I honestly don't</p> <p>12 know. NDC tends to electropolish most of their</p> <p>13 products, so I imagine it was, but I don't know for</p> <p>14 certain.</p> <p>15 Q. At least during some period of time when Dr.</p> <p>16 Robertson was employed by NDC, NDC was owned by Cordis,</p> <p>17 correct?</p> <p>18 A. Yes. Yes.</p> <p>19 Q. Are you aware that Cordis manufactures a --</p> <p>20 one or more inferior vena cava filters?</p> <p>21 A. Yes. I have become aware. I didn't know</p> <p>22 until recently. Yes.</p> <p>23 Q. You do a fair amount of work, I believe you</p> <p>24 indicated, for Cordis?</p> <p>25 A. I have been their consultant, and they now</p>



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<p>1 send me small gift money to -- that I work at the 2 University on. 3 Q. Has Dr. Robertson seen your report in this 4 litigation, to your knowledge? 5 A. No. I haven't sent it to them, certainly. 6 Q. So he's made no revisions or comments or 7 suggestions on your report? 8 A. No. In fact, other than the typos from Mr. 9 Hartley and Mr. Jack Davis, no one has made any 10 comments -- oh, apart from your expert, of course. 11 Q. You do not have any training in epidemiology, 12 do you? 13 A. No. 14 Q. Would you agree with this as a general 15 proposition in your field that cracks always exist in 16 materials? 17 A. Yes. 18 Q. And that -- would you agree that components 19 must be tolerant of the presence of cracks? 20 A. Ideally, yes. 21 Q. You have done some study and analysis and 22 publication regarding the fracture of Nitinol stents, 23 correct? 24 A. It is mainly on fracture of Nitinol, on the 25 wire-type material used to make stents. The one topic</p>	<p>1 because with Nitinol, it changes with product form. 2 So what's called a diamond sample has been 3 generated, which is an enlarged version of the 4 stent-like form. And that's where most of the fatigue 5 testing has been done for stents, on these diamond 6 samples, and we examine that diamond sample. It not an 7 actual stent, but it is made from the same materials as 8 the stent, and it's in the image of a stent, and that 9 is basically the fundamental unit that we look at. 10 And that particular paper you are referring to 11 involves numerical analysis of the stresses in that 12 stent and the -- in that stent-like device or diamond 13 device, and a simultaneous examination with the X-ray 14 synchrotron up at LBL. 15 Q. And in that study -- let me just hand it to 16 you. It is Mehta. I have got it right here. 17 MR. NORTH: If we could mark this as Exhibit 18 4. 19 (Whereupon Defendants' Exhibit No. 20 4 was marked for identification.) 21 BY MR. NORTH 22 Q. I am sorry, you will get the one that is 23 actually marked. Let me give this to Dean. 24 MR. HARTLEY: 3 was the report? 25 MR. NORTH: 3 was the report, yes.</p>
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<p>1 that I wrote specific to stents was on the life 2 prediction of those stents, which is an article that 3 was published in Biomaterials a few years ago. 4 Q. What about an article you co-authored with a 5 Dr. Mehta regarding understanding the defatation and 6 fracture of Nitinol in endovascular stents? 7 A. Yeah. That was -- again, I am using the 8 differential pertaining to stents. That was involving 9 a certain geometry -- a stent-like geometry which we 10 looked at in the synchrotron to understand how the 11 stress analysis related to the transformations in the 12 stent. So, yeah, all of the work I have done recently 13 pertains to stents, but it isn't necessarily -- the 14 only one that is specifically on stents is the one on 15 life prediction. I mean, I don't pull the test stents. 16 I examine the wire used to make the stents. 17 Q. Well, in your testing, in your article with 18 Dr. Mehta, you talked about testing that had been 19 done -- modeled -- or modeling, finite element analysis 20 that had been done to try to gauge the strength of the 21 stent. 22 A. Let me explain this, what happens here. The 23 stents are very, very small. I mean, the wire -- so 24 one of the philosophies that's been used to evaluated 25 that material -- you need to test the actual material,</p>	<p>1 BY MR. NORTH 2 Q. And this is the article that -- and the study 3 that we were just referencing that you conducted with a 4 number of folks, including Dr. Mehta, correct? 5 A. Indeed. 6 Q. If I could draw your attention to the first 7 page, the second column, under "Stent Design." 8 A. Yes. 9 Q. If you would read that paragraph to yourself, 10 please. 11 A. Okay. 12 Q. And there you are talking about the fact that 13 finite element analysis conducted on stent designs or 14 stent materials sometimes don't prove to be true for 15 the actual stent when implanted, correct? 16 A. No. I don't say that. I mean, the issues 17 here are that -- numerical analysis is now the 18 preferred way of doing any stress analysis. And with 19 certain situations, it is a little bit more difficult 20 to do this analysis. And certainly with Nitinol, there 21 is this question of the fact that it has what is called 22 superelasticity. 23 So the -- this is a difficult thing to deal 24 with. And, in fact, the people at Abacus, who are the 25 premiere numerical stress analysis company, they have</p>

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<p>1 spent a lot of time trying to focus on how to develop 2 the constitutive laws for Nitinol devices, so I don't 3 think they're -- there is still stuff to be done there 4 with respect to the multiaxial aspects. 5 But what we were trying to do in this 6 particular paper is to see how far those analyses can 7 go and whether they are consistent with what we 8 understand from the microstructural changes in the 9 material. 10 Q. If I understand what you are saying now, what 11 you are saying in this paragraph, you are saying that 12 despite everyone's best efforts, these mathematical 13 computations of how -- at least with a Nitinol stent 14 material -- how it may perform in the human body 15 sometimes is not quite consistent with the actual 16 experience once -- can I finish my question, please? 17 A. Sorry. 18 Q. Not quite consistent with the experience once 19 the device is implanted? 20 A. Well, the issue there is, the numerical 21 analysis can't tell you what the physiological loads 22 are. So that's where -- a lot of the uncertainty comes 23 in certain people's calculations in estimating what the 24 physiological loads are. 25 Q. I think that is exactly what I was trying</p>	<p>1 thromboid? So those are the physiological inputs, and 2 they are much more difficult to get. But that has 3 nothing to do with the numerical; it is the input to 4 the numerical analysis. 5 Q. So designers obviously should use their 6 absolute best efforts to try to approximate what those 7 physiological loads are, but you just indicated that it 8 is difficult to do so? 9 A. No. I said -- I said -- obviously they have 10 to do -- in any design, you have to approximate what 11 the loads are in that device. But it is -- it is 12 difficult in any situation, whether you are designing 13 an airplane or whether you are designing a medical 14 device. But the numerical analysis does not do that; 15 the numerical analysis takes those inputs and computes 16 them into stresses or strains in the device itself. 17 Q. So in talking about this phenomenon, the 18 difficulty in quantifying the physiological loads, you 19 indicated in this paper that's been marked as Exhibit 4 20 that with regard to stents fracturing, we, and I quote, 21 "We may conclude that either our knowledge of the 22 nature and magnitude of the deformation of a stented 23 artery is incomplete, or current finite element models 24 fail to fully represent the actual mechanical response 25 of a Nitinol stent." Correct?</p>
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<p>1 to -- 2 A. It is not the analysis, per se. It is the 3 fact that -- it is the inputs to the analysis. There 4 are a few problems with Nitinol; it is much more 5 complicated than regular materials. But the bigger 6 problem, I think, is the physiological aspects. 7 Q. So numerical analyses cannot with complete 8 accuracy quantify the physiological stresses that occur 9 inside the human body? 10 A. What do you mean by "complete accuracy?" 11 Nothing has complete accuracy. But the issue is, if 12 you are trying to calculate the stresses in a medical 13 device, you -- there are two principle inputs. One is 14 the computation of the stresses, which is where the 15 numerical analysis comes in, and the constitutive 16 behavior of material and all that aspect. 17 The second one that is, what are your boundary 18 conditions? What loads you are putting in? And so the 19 loads that the medical device experiences are 20 associated with the physiological aspects of the 21 environment it sits in. 22 So any designer of a medical device, it is 23 really incumbent upon them to understand what those 24 various modes are. Is it a heart valve? Is it the 25 regurgitation of the blood? Is it the impact of a</p>	<p>1 A. And the rationale for that is that until 2 fairly recently, all stents were designed on the basis 3 of the pulsatile loading of the flexure of the artery 4 on the cardiac cycle. And there has been a lot of work 5 now done on trying to measure the actual stresses and 6 displacements inside arteries. 7 And there is indications that one should take 8 into account -- which should have been done before -- 9 of things like tensile loads and bending loads. That's 10 what that paper that I wrote recently on multiaxial 11 loading tends to address. 12 Q. So the scientific community, its knowledge of 13 the physiological loads put on the stent when implanted 14 is evolving and improving as time goes on? 15 A. Everything is evolving and improving. I mean, 16 that is not peculiar to this situation. Our state of 17 knowledge grows in everything. The issue is that when 18 you design something from an engineering perspective, 19 one has to be sufficiently conservative to take into 20 account all of the imponderables, and there are always 21 imponderables in real-life devices. There is no such 22 thing as black and white; everything is gray. This is 23 not like physics and chemistry. 24 So when you design a bridge, you don't know 25 exactly what the loads are going to be, but you make</p>

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<p>1 certain that you put in sufficient safety factors, or  2 you put in consideration of worst-case scenarios to  3 take into account for that. It is very standard  4 procedure.  5 Q. You have been involved with stents for a  6 number of years, correct?  7 A. Yes.  8 Q. Ten years?  9 A. Yes, probably. Yes.  10 Q. And you would agree that we know much more  11 about the physiological stresses placed on stents when  12 implanted today than we did when we first -- you first  13 started -- when you first became involved with those  14 sorts of products around 10 years ago?  15 A. I don't know for certain, but I would imagine.  16 I haven't worked on the measurement of physiological  17 loads and so forth, so I don't know precisely. I mean,  18 one tends to try and simulate these impulse duplicators  19 and so forth. But it would be very unusual if nothing  20 further has been known or gleaned in the last 10 years.  21 Q. Now, Dr. Ritchie, you were just saying you  22 published recently about -- what did you just call it,  23 multiaxial --  24 A. I didn't publish about the physiological  25 loads. I merely published the means of doing a life</p>	<p>1 situation before.  2 I mean everything contains cracks. If those  3 cracks are large enough that they lead to the failure  4 of that device, then it is certainly defective. But to  5 say that if every component that contains a crack is  6 defective, then everything around us is defective. You  7 can't put a black and white on that.  8 Q. Let me pose it to you this way, and I think  9 you just answered this, but to use this terminology, do  10 you believe that all cracks pose hazards?  11 A. Potentially all cracks pose hazards. But the  12 reality is that -- if those cracks are small enough or  13 in situations where they are not activated by the  14 stresses, then they would not pose a hazard. So again,  15 you are trying to put a black and a white perspective  16 on something which is neither black or white. Somebody  17 once asked me, "Are cracks beneficial?" You know, and  18 it is an impossible question; it is like saying, "Is  19 aging beneficial." It is a fact of life.  20 Q. Do you believe that product manufacturers can  21 create products that are immune to crack initiation?  22 A. One would hope that they could do that, but it  23 is -- when you develop a product that sees a certain  24 environment, I think it is incumbent upon you as a  25 designer or as a manufacturer to make certain that</p>
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<p>1 prediction in light of the fact there is multiaxial  2 loads there.  3 Q. But that reflected the evolving understanding.  4 I mean, the premise when you are looking at multiaxial  5 loads reflects the evolving understanding of what sort  6 of stresses are put on stents when implanted, correct?  7 A. Yeah, but that wasn't necessarily my  8 motivation. My motivation was that things go in  9 stages. With all things, you look at uniaxial motions  10 first, and I looked at multiaxial motions. I realized  11 that no one had done that for stent-like devices, so  12 that's why I looked at that analysis. But, I mean,  13 certainly there have been many studies done in the last  14 decade. I am sure there is more known now than there  15 was then.  16 Q. Do you believe that just because a device has  17 a crack in it of some nature, that it is defective?  18 A. That is a very impossible question to answer  19 because everything contains a crack. And a crack is  20 referred to in the general vernacular as a defect. And  21 so it is a question of whether that crack is dangerous  22 or not. There is cracks in that chair that you are  23 sitting in, but it is not necessarily dangerous because  24 they're not big enough to be activated by your weight  25 on the stresses on the chair. I have been put in this</p>	<p>1 those cracks that inevitably may be there or may form  2 in service are not likely to cause failure during the  3 time they are in the patient.  4 So one of the things that I try to do is do  5 life predictions, so you can -- for a heart valve or a  6 stent, you can predict the life, and you hope that life  7 would be longer than the patient lifetime.  8 Q. I believe you said earlier that cracks always  9 exist in materials.  10 A. Yes, always. I mean, there is no such thing  11 as a perfect material.  12 MR. NORTH: I'm sorry. I think it is a good  13 time to take a break.  14 THE VIDEOGRAPHER: This concludes Video No. 1  15 of the deposition of Robert Ritchie. Going off the  16 record. The time on the monitor is 11:05 a.m.  17 (Off the record from 11:05 a.m.  18 to 11:21 a.m.)  19 THE VIDEOGRAPHER: Here begins Video No. 2 of  20 the deposition of Robert Ritchie, coming back on the  21 record. The time on the monitor is 11:21 a.m. Please  22 begin.  23 BY MR. NORTH  24 Q. Doctor, I would like to turn now to the  25 substance of your report with regard to your opinions.</p>

20 (Pages 77 to 80)

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<p>1 A. Okay.</p> <p>2 Q. And your report has been marked to the</p> <p>3 deposition as Exhibit 3. In your report, you state</p> <p>4 that the recovery filter has a 21 to 31.7 percent rate</p> <p>5 of fracture and/or migration of parts of the device; is</p> <p>6 that correct?</p> <p>7 A. Yes.</p> <p>8 Q. And where did you draw those particular</p> <p>9 numbers from?</p> <p>10 A. From Reference 6, I believe.</p> <p>11 Q. I'm sorry. Reference 6?</p> <p>12 A. Yes. I think -- I mean, I drew those from the</p> <p>13 published literature on -- that is why there is a range</p> <p>14 here. I know the Hull and Robertson paper, on the</p> <p>15 basis of the ones they looked at was about 20 percent.</p> <p>16 Q. So you are saying that Reference 6 is the</p> <p>17 support for the statement that data suggests that the</p> <p>18 recovery filter has a 21 to 31.7 percent rate of</p> <p>19 fracture and/or migration of parts of the device?</p> <p>20 A. Yes. That's how I understand it, yes.</p> <p>21 Q. And that is the Kalva article, correct?</p> <p>22 A. Yes. There was also statistics in Hull's</p> <p>23 article as well, Hull and Robertson.</p> <p>24 Q. But your paper doesn't cite Hull there, does</p> <p>25 it?</p>	<p>1 research coordinator?</p> <p>2 A. No. I would hope that his published paper,</p> <p>3 though, would be accurate in that regard.</p> <p>4 Q. But you don't have any independent knowledge</p> <p>5 as to whether it is, do you?</p> <p>6 A. I have to look at the peer-reviewed</p> <p>7 literature, and I would -- and I would take that as a</p> <p>8 good source. That's what I have done here.</p> <p>9 Q. So if I understand what you are saying is,</p> <p>10 because Dr. Nicholson's article has been peer-reviewed,</p> <p>11 you would assume that it is a valid study?</p> <p>12 A. Depends on what you mean by "valid." But</p> <p>13 certainly if I am -- I was interested to know roughly</p> <p>14 what the rates of failure of these devices are, and I</p> <p>15 went to the literature, and Nicholson's article was one</p> <p>16 such referenced source. So I would have to assume it</p> <p>17 was right.</p> <p>18 Q. Your statement mentions that the fracture --</p> <p>19 reported fracture rate of the recovery filter goes as</p> <p>20 high as 31.7 percent. Do you know where you got that</p> <p>21 number?</p> <p>22 A. I have forgotten the exact -- it is on the</p> <p>23 basis of one of these studies. You know, the problem</p> <p>24 here is that each study has a limited number of</p> <p>25 examinations, and so the numbers would vary depending</p>
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<p>1 A. Not on that particular point, no.</p> <p>2 Q. Now, you also read Dr. Nicholson's article?</p> <p>3 A. Yes.</p> <p>4 Q. And, in fact, you cite that later in the same</p> <p>5 paragraph on Page 2 of your report, where you talk</p> <p>6 about the G2 device and say that it has been associated</p> <p>7 in the literature with a 12-percent rate of fracture</p> <p>8 and stress of the filter, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And Nicholson is our support for that</p> <p>11 statement?</p> <p>12 A. Yes. I think so, yes.</p> <p>13 Q. You have not conducted any independent studies</p> <p>14 to try to determine the fracture rate, if any, of the</p> <p>15 recovery of G2 filters, have you?</p> <p>16 A. Of course not.</p> <p>17 Q. And you are relying solely on these articles</p> <p>18 that you have cited, correct?</p> <p>19 A. Absolutely. Yes. I hope I cited them</p> <p>20 correctly, but certainly in those articles it gives</p> <p>21 some estimates of the failure rates, and those are the</p> <p>22 ones I have cited.</p> <p>23 Q. And while you have relied upon Dr. Nicholson's</p> <p>24 article as one of the bases for those statements, you</p> <p>25 have not read his deposition or the deposition of his</p>	<p>1 on the small sample statistics. So whether it is 21 or</p> <p>2 31.7, it depends somewhat on the population of filters</p> <p>3 that were examined.</p> <p>4 Q. And all of these studies were single-site</p> <p>5 studies, correct?</p> <p>6 A. What does that mean?</p> <p>7 Q. Looking at procedures done at one facility.</p> <p>8 A. I can't recall. It is possible. I don't</p> <p>9 know.</p> <p>10 Q. So you have not tried to analyze these studies</p> <p>11 from an epidemiological standpoint, have you?</p> <p>12 A. Of course not, no. In my opinion, if those</p> <p>13 failure rates are even close to those numbers, then</p> <p>14 that is a severe problem. Whether they are 20 or 30 is</p> <p>15 almost academic.</p> <p>16 Q. Do you recall how many filters were involved</p> <p>17 in the Hull and Robertson study?</p> <p>18 A. No, I don't, offhand. I can check for you if</p> <p>19 you are interested.</p> <p>20 Q. That is okay. Well, do you recall that Hull</p> <p>21 and Robertson recognized that their patient cohort was</p> <p>22 too small to allow definitive assessments from their</p> <p>23 data?</p> <p>24 A. I mean, with the medical industry you are</p> <p>25 never quite certain what small and large is, so, as I</p>



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<p>1 said earlier, each of these studies has looked at a  2 limited number of filters. And so one would hope that  3 they would give a rough indication of what the overall  4 failure rates are, but without looking at all of them,  5 one can never be quite certain.</p> <p>6 Q. Doctor, if you knew that in one of the studies  7 that out of 13 fractured filters, 10 had been implanted  8 by a single physician, would that cause you some  9 concern about the validity of that data?</p> <p>10 A. Possibly. I mean, I am not going to argue  11 with you whether it is 21 or 31 percent. I think that  12 is somewhat academic here to my analysis. But in an  13 ideal world, you would like a somewhat larger  14 statistical population. If you want a definitive  15 number of the failure rates, then I was not given that  16 opportunity to have that information.</p> <p>17 Q. I don't think that was my question, Doctor. I  18 didn't ask you about anything about the 21 to  19 31 percent. My question is very narrow and very  20 simple.</p> <p>21 If you were to learn that in a study involving  22 13 fractured filters, 10 of the filters that fractured  23 had been implanted by a single physician, would that  24 cause you some concern about the validity of the data  25 in that study?</p>	<p>1 specifically at that aspect, no.</p> <p>2 If the failure rates of all IVC filters are  3 around 30 percent for all devices, for all  4 manufacturers who make these filters, there is  5 something seriously wrong.</p> <p>6 Q. You keep mentioning the 30 percent.</p> <p>7 A. Have 20 percent. Have 10 percent. I don't  8 care what you say, 10, 20, 30 percent, in my opinion,  9 that is an unacceptable -- would you like one of these  10 things put inside you if you knew that --</p> <p>11 Q. I am going to object to this.</p> <p>12 A. Seriously. You asked me a question. I am  13 telling you the answer. I don't care if it is 10  14 percent, 20 percent, or 30 percent. Personally, I  15 think that is an unacceptable failure rate.</p> <p>16 MR. NORTH: Doctor, before you gave -- I first  17 move as nonresponsive. There wasn't even a question on  18 the table. I have made one statement that was --  19 before I even finished my question, I said you have  20 mentioned this 30-percent fracture rate. You then  21 launched into that speech. We have every intent of  22 finishing this deposition by this afternoon, but if you  23 don't listen and answer my question and just give  24 speeches unrelated, we'll never get finished. We'll be  25 here for days.</p>
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<p>1 A. I would question it, certainly. But I  2 question all data. That is part of the scientist's  3 job.</p> <p>4 Q. Are you aware of the fact that all inferior  5 vena cava filters fracture to some extent?</p> <p>6 A. All? I mean, that is a question that no one  7 can answer.</p> <p>8 Q. All brands of filters?</p> <p>9 A. Well, I am not privy to all brands of filters,  10 so it is very difficult to answer that question.</p> <p>11 Q. So you have done no study as a part of your  12 work in this case as to whether other manufacturers'  13 filters fracture on occasion?</p> <p>14 A. I have not looked directly at that. There has  15 been peripheral information in some of the depositions,  16 but my emphasis has been to try and find out why these  17 filters fractured.</p> <p>18 Q. So as you sit here today, you have no personal  19 knowledge one way or the other as to whether the  20 fracture rates of the Bard filters exceed or are less  21 than the fracture rates of competitive IVC filters?</p> <p>22 A. I have not seen specific statistics. I think  23 if the fracture rates in the other filters had been as  24 high as the ones that appear to be for the Bard filter,  25 I would know about it, but I haven't looked</p>	<p>1 Now, that being said, my question is, you have  2 mentioned 30 percent several times. And based on your  3 report, it is my understanding that you believe at  4 least one of the studies supports a fracture rate of  5 the recovery filter of 31 percent; is that correct?</p> <p>6 A. I wouldn't have made it up. Yes.</p> <p>7 MR. NORTH: Okay. Would you mark this as the  8 next exhibit, please?</p> <p>9 (Whereupon Defendants' Exhibit No.  10 5 was marked for identification.)</p> <p>11 BY MR. NORTH</p> <p>12 Q. Let me hand you what's been marked as  13 Exhibit 5. And based on the list the attorneys  14 provided us of the materials that you were given, my  15 understanding is that you were not provided with this  16 report and therefore have not seen this; is that  17 correct?</p> <p>18 A. No. I haven't seen it.</p> <p>19 Q. I'm sorry, what is that?</p> <p>20 A. I haven't seen it, no.</p> <p>21 Q. So you are not familiar with the reported  22 fracture rates for inferior vena cava filters as a  23 whole?</p> <p>24 A. I don't know the basis of the question. I  25 mean, does this report refer to those rates?</p>

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<p>1 Q. That wasn't my question. My question to you 2 was are you familiar with the reported fracture rates 3 of inferior vena cava filters as a class or product? 4 A. As much as they have been mentioned in 5 published papers on the failures of these filters, I 6 have, yes. I mean, how else can I answer that 7 question? I have looked at the literature, and I have 8 seen rates of failed filters, and I have quoted a range 9 there that I found from the papers. 10 Q. I am not talking about the Bard filters; I am 11 talking about all filters as a class of products. 12 A. No, I am not familiar with them. Sorry, I 13 misunderstood you. 14 MR. NORTH: Could we mark this as the next 15 exhibit, No. 6, please? 16 (Whereupon Defendants' Exhibit No. 17 6 was marked for identification.) 18 BY MR. NORTH 19 Q. Doctor, let me hand you what has been marked 20 as Exhibit 6, which is an article called "Quality 21 Improvement Guidelines for Percutaneous Permanent 22 Inferior Vena Cava Filter Placement." My understanding 23 is that the attorneys did not provide you with a copy 24 that document either, did they? 25 A. No.</p>	<p>1 planes of atoms slide over one another. And if the 2 slip bands are particularly well-formed, then you can 3 see cracking along those regions. That's what 4 slip-band cracking is. 5 Q. Are slip bands fairly normal on Nitinol 6 surfaces? 7 A. If it is failing, yeah. They are generally 8 indicative of pretty high strain. 9 Q. Did you observe slip-band cracking on all the 10 filters you examined? 11 A. I can't recall exactly, because there was 12 12 of them. But in a lot of them, certainly, yes. 13 Q. Did you find slip-band cracking on the 14 exemplar filters? 15 A. I think there was some evidence of that on the 16 exemplars. Just give me a second to look here. Yeah, 17 there was slip bands on those. 18 Q. Are slip bands something that you would expect 19 to see on a Nitinol medical device that has been in 20 situ for a lengthy period? 21 A. Possibly. I mean, that is a very difficult 22 question to answer. It depends on the loads, the 23 stresses, the period. I mean, you know, if things are 24 allowed to deform and ultimately fail, then you 25 probably see slip-band cracking. If the stresses or</p>
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<p>1 Q. Are you familiar with Dr. Clement Grassi? 2 A. No. 3 Q. Other than Dr. Kaufman, whose deposition you 4 are in the middle of reading, do you know of any other 5 leading interventional radiologists in the field? 6 A. No. 7 Q. You haven't spoken to any interventional 8 radiologists that may be affiliated with Berkeley here, 9 have you? 10 A. No. 11 THE VIDEOGRAPHER: Would you raise your 12 microphone? 13 MR. NORTH: I'm sorry. 14 THE VIDEOGRAPHER: That is okay. 15 BY MR. NORTH 16 Q. Your report talks in terms of slip-band 17 cracking. 18 A. Uh-huh. 19 Q. Can you explain to me what that is? 20 A. It is a process whereby in Nitinol materials, 21 you often get cracking on the surface which forms on 22 slip bands. 23 Q. What is a slip band? 24 A. Materials deform by a process of slip, just 25 like a pack of cards. On an atomistic level, the</p>	<p>1 loads they see are very small, you possibly wouldn't. 2 If they were deformed during manufacture, it is 3 possible you would see -- so it is too much of a 4 generalization. You can't answer a question like that. 5 Q. In your work with stents, have you seen 6 slip-band cracking on Nitinol stents that have been in 7 situ? 8 A. I haven't looked at many stents that have been 9 explanted in situ. I haven't looked at many stents at 10 all in that regard. So I don't recall any slip-band 11 cracking. I don't have enough experience to look at 12 those ex situ, explanted stents. 13 Q. Have you, in the course of your career, ever 14 done any sort of microscopic analyses of explanted 15 stents such as you have with regard to these filters 16 here? 17 A. Stents, no. 18 Q. Stents. 19 A. I have looked at stents before they are put 20 in. You don't see many explanted stents. They are not 21 generally explanted, so I don't know many studies that 22 have looked at that, quite frankly. A stent is not 23 such a critical device. They break occasionally, but I 24 have been more concerned with looking at the 25 manufacture of them and looking at some of the cracking</p>



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<p>1 procedures during the manufacture of these stents.</p> <p>2 Q. Doctor, you've told what the literature says.</p> <p>3 You've told me these things aren't normally explanted,</p> <p>4 but you haven't answered the very simple question.</p> <p>5 Have you personally ever examined,</p> <p>6 microscopically, an explanted stent such as you did</p> <p>7 with the filters removed in this case?</p> <p>8 A. No.</p> <p>9 Q. Have you ever analyzed any explantable --</p> <p>10 explanted Nitinol medical device except for the --</p> <p>11 other than the filters that you have looked at as a</p> <p>12 part of this case?</p> <p>13 A. I worked for a company who were in the early</p> <p>14 days of the production of Nitinol stents. And I may</p> <p>15 have looked at -- it was explants from, I think, sheep,</p> <p>16 I may have done. I can't quite recall. I think it was</p> <p>17 explanted sheep stents. That was a long time ago in</p> <p>18 the early days. They were worried about the laser</p> <p>19 cutting of the stents. And I think I may have looked</p> <p>20 at explanted stents at that point, but not from humans,</p> <p>21 no.</p> <p>22 Q. And that would be with regard to any explanted</p> <p>23 Nitinol device. Other than the sheep stents you just</p> <p>24 referenced and the filters involved in this case, you</p> <p>25 have never done a microscopic analyses -- or analysis</p>	<p>1 Q. I'm sorry, what?</p> <p>2 A. No.</p> <p>3 Q. That is not your opinion, then?</p> <p>4 A. I don't have an opinion on that, quite</p> <p>5 frankly. I mean, slip-band cracking is simply evidence</p> <p>6 of some kind of prior defamation or some defamation or</p> <p>7 service of prior defamation from the manufacturer. And</p> <p>8 to say that you could make a generalization that all</p> <p>9 devices could have no prior defamation is, again, way</p> <p>10 too much of a generalization.</p> <p>11 Q. And just because a device has evidence of</p> <p>12 slip-brand cracking prior to use does not mean it is</p> <p>13 necessarily going to fail in actual use, does it?</p> <p>14 A. No, of course not.</p> <p>15 Q. With the explanted filters in which you saw</p> <p>16 slip-band cracking, are you able to say one way or the</p> <p>17 other whether that slip-band cracking existed prior to</p> <p>18 implantation?</p> <p>19 A. You can't be precise. It would be very</p> <p>20 difficult to indicate whether it occurred during</p> <p>21 service or prior to.</p> <p>22 Q. And actually, it would require you to actually</p> <p>23 inspect it or examine the filters prior to implant to</p> <p>24 be able to say whether the slip-band cracking</p> <p>25 preexisted the implant, correct?</p>
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<p>1 of explanted Nitinol medical devices in the past?</p> <p>2 A. Nitinol medical devices -- let me think here</p> <p>3 for a second. The only medical devices that have been</p> <p>4 made that I work with here would be stents, and I</p> <p>5 don't -- apart from those sheep stents, I don't think I</p> <p>6 have looked at any explanted stents.</p> <p>7 Q. So my statement is correct: The sheep stents</p> <p>8 and the filters in this case are the only Nitinol</p> <p>9 medical devices that have been explanted at the time</p> <p>10 that you have examined them microscopically?</p> <p>11 A. I think that is the case. I can't recall.</p> <p>12 Q. Did you see this slip-band cracking on all of</p> <p>13 the exemplars you examined?</p> <p>14 A. I can't recall exactly. I can refer to my --</p> <p>15 to all of my figures. I only looked at two or three,</p> <p>16 so I can't recall if they were on every one.</p> <p>17 Q. Was the evidence of slip-band cracking as</p> <p>18 severe on the exemplar filters as it was on the</p> <p>19 explanted filters?</p> <p>20 A. I think it was -- I mean, it would be fair to</p> <p>21 say it would be somewhat more severe on the explanted</p> <p>22 filters.</p> <p>23 Q. Is it your opinion that no medical device</p> <p>24 should exhibit any slip-band cracking prior to use?</p> <p>25 A. No.</p>	<p>1 A. To be 100 percent certain, absolutely.</p> <p>2 Q. You also report that you see surface gouges in</p> <p>3 some of the recovery filters; is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. Did you observe these gouges in every filter?</p> <p>6 A. Of the recovery ones, again, I am not</p> <p>7 absolutely certain, but they were very prevalent in</p> <p>8 certainly most of them. I looked at six. I can't tell</p> <p>9 you exactly what they were in every one, but they were</p> <p>10 in most of them, certainly.</p> <p>11 Q. Were they present in the exemplar filters?</p> <p>12 A. Yes. Yes, they were.</p> <p>13 Q. Did you take precise measurements of any of</p> <p>14 these surface gouges?</p> <p>15 A. Other than taking -- it is very difficult to</p> <p>16 do that unless you use a profilometer. So you can see</p> <p>17 the measurements from the scanning electron microscope</p> <p>18 I didn't actually document those -- the depths of those</p> <p>19 gouges.</p> <p>20 Q. Did you make any analysis or tests to</p> <p>21 determine what may have caused those gouges?</p> <p>22 A. You can't do an analysis. I didn't do an</p> <p>23 analysis or test. I can't destructively affect these</p> <p>24 filters. But my opinion is that they were -- since</p> <p>25 they tend to form around the bend in the arm, they were</p>

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<p>1 almost certainly done during the shape-setting 2 procedure where they bend the arm to a particular 3 shape. That's what it looks like. 4 Q. So the gouges that you saw, surface gouges, 5 were concentrated in the area around the bend of the 6 arm? 7 A. That is typically -- there may have been other 8 places as well, but a lot of them were formed there. 9 Q. Did you see any surface gouges on the legs of 10 the filters? 11 A. No. I mean, there is a lot of other 12 defects -- I shouldn't say defects -- there is a lot of 13 other markings which are associated with the centerless 14 grinding and the draw-marks and so forth. There may 15 well have been small gouges down there. But the ones 16 that seemed to me to be the more -- ones that we would 17 have concern about were around the bend in the arm. 18 Q. Do you have any idea of how the actual 19 assembly line -- excuse me -- process for the 20 manufacturer of these filters operates? 21 A. Well, I have looked at what was given to me in 22 some of the documentation, and its pretty standard for 23 these Nitinol devices. You tend to deform them to a 24 particular shape, and then you give what is called a 25 shape-setting procedure which is an anneal, typically</p>	<p>1 A. Yeah. There is -- again, the documentation 2 that was sent to me, it is not very clear, by the way. 3 But there is some sort of rig they set up where they 4 put the filter in, and then they -- I think they bend 5 the arms in that particular rig. 6 Q. Okay. You make the following statement in 7 your report. You say, "Although the location of the 8 fatigue crack initiation sites could not always be 9 clearly identified with such surface damage, there is 10 evidence of such an association." I'm sorry. Look on 11 Page 6 of your report, if you would. 12 A. Can you -- which -- 13 MS. HELM: Get the page numbers. 14 THE DEPONENT: Where are you? 15 BY MR. NORTH 16 Q. It is the one that has this picture at the 17 bottom. 18 MR. HARTLEY: Figure 6? 19 MR. NORTH: Yeah. 20 THE DEPONENT: Figure 6. 21 BY MR. NORTH 22 Q. Okay. 23 A. Okay. 24 Q. About midway through that paragraph, where it 25 says, "Although the location of the fatigue crack</p>
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<p>1 about 500 degrees Centigrade, which then sets that 2 shape. And I have seen a drawing of a rig that I think 3 that Bard used to do this. So insomuch, I have a 4 general idea how they did that, yes. 5 Q. I think it is clear from your report, but I 6 just want to make sure. You don't have any criticism 7 of the use of Nitinol in a filter, do you? 8 A. No. 9 Q. And properly done, in accordance with how you 10 think it should be treated and created, Nitinol is an 11 acceptable material for an inferior vena cava filter, 12 correct? 13 A. Yeah. Quite frankly, I think if you are going 14 to have a recoverable filter, then it is probably the 15 best way to go. 16 Q. So I believe you just said a minute ago that 17 you suspect that the gouge marks were -- around the 18 arms were caused in the process of bending the arms? 19 A. That is what I think it was caused by. I 20 mean, I don't know for certain, because no one can know 21 for certain other than perhaps Bard, but it would seem 22 to me that is most likely where those marks were 23 formed. They are certainly unusual. 24 Q. Do you have any understanding of what kind of 25 machine is used to bend those arms?</p>	<p>1 initiation sites could not always be clearly identified 2 with such surface damage, there is evidence of such an 3 association in Figure 10. The presence of such surface 4 markings is certainly not beneficial to the durability 5 of the device." Is that correct? 6 A. Yes, indeed. 7 Q. If I understand what you are saying there, you 8 are saying that these surface gouges you saw were not 9 always in every filter related to -- appeared to be 10 related to the actual fracture? 11 A. That is right. 12 Q. Can you tell me how many of the filters you 13 believe there was an association between the surface 14 gouge and the fracture? 15 A. Can I look at the crib sheet I made of this? 16 Q. Yeah. 17 A. So I looked at 11 filters, 6 of which were 18 recovery. 19 Q. Okay. 20 A. And by my assessment, there were three types 21 of failure modes that you can delineate. And one of 22 those failure modes was -- involved, I think, a clear 23 association with a defect, a surface gouge and a 24 fatigue failure. And out of the eleven I looked at, 25 three -- two recovery and one G2 -- I think you can</p>

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<p>1 attribute it to one of those gouges.</p> <p>2 There is a -- there is a fourth one which your</p> <p>3 expert indicated, associated with an inclusion, which</p> <p>4 is effectively a defect. And maybe she is right and</p> <p>5 maybe she is not, but I don't really have much of an</p> <p>6 opinion of that because you'd need to do an x-ray</p> <p>7 analysis to see that that inclusion was there. But so</p> <p>8 I can definitely say that 3 out of the 11, the failure</p> <p>9 of one of the arms can be attributed to a defect.</p> <p>10 Q. What are the other two failure modes that you</p> <p>11 just mentioned, did you identify?</p> <p>12 A. Well, there is -- one failure mode involves</p> <p>13 the initiation of fatigue crack at the rim.</p> <p>14 Q. The --</p> <p>15 A. The rim or the sheath, whatever you call it,</p> <p>16 where the wires emerge from the rim. And it looks like</p> <p>17 that is where the wire is in contact with the rim.</p> <p>18 There is a sharp corner there, as you know. So that is</p> <p>19 not a particularly good design. And so the cracks tend</p> <p>20 to start there, and then they propagate from the</p> <p>21 outside of the device to the inside of the device.</p> <p>22 This is -- I am talking about the arms now -- that is a</p> <p>23 second failure mode.</p> <p>24 Q. How many of those did you perceive --</p> <p>25 A. Again, out of the -- out of the -- I am going</p>	<p>1 arms?</p> <p>2 A. Yes.</p> <p>3 Q. Some of these had multiple-fracture arms?</p> <p>4 A. Yes.</p> <p>5 Q. How many arms did you see an association</p> <p>6 between the surface -- a surface gouge and the</p> <p>7 fracture -- in the recovery filters only?</p> <p>8 A. There were two failures out of all of the arm</p> <p>9 failures that one could -- I can attribute to a surface</p> <p>10 gouge, and there was this additional one that your</p> <p>11 expert indicated from an occlusion.</p> <p>12 Q. So you have two of the arms that you believe,</p> <p>13 in your view, had an association between a surface</p> <p>14 gouge and a fracture?</p> <p>15 A. In the recovery filters.</p> <p>16 Q. In the recovery filters?</p> <p>17 A. Uh-huh.</p> <p>18 Q. And you believe that two of them -- and you</p> <p>19 talked about the rim. I believe some of the literature</p> <p>20 or some of the specifications talk in terms of the</p> <p>21 sleeves?</p> <p>22 A. Sleeve or sheath.</p> <p>23 Q. You saw two that you believe the crack</p> <p>24 initiated at the sleeve; is that correct?</p> <p>25 A. Yes. I mean, there are basically of the --</p>
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<p>1 to leave the G2s out, because several of the G2s didn't</p> <p>2 even fail, at least in the arms. Out of the six</p> <p>3 recoveries, two can definitely be attributed to the</p> <p>4 contact. There are three other arms where the cracks</p> <p>5 do propagate from the rim side inwards, which is</p> <p>6 somewhat unusual in terms of the loading of the device.</p> <p>7 And the third mode is the one that you would</p> <p>8 probably think would be the most likely, is where the</p> <p>9 cracks initiate on the inside of the wire of the filter</p> <p>10 and propagate to the outside. And they are the most</p> <p>11 prevalent ones. And I counted basically five arms</p> <p>12 failing in that fashion.</p> <p>13 And the initiation of the cracks, they are a</p> <p>14 little bit more difficult to find out, but it appears</p> <p>15 to be where the arms touch or maybe rub together. I</p> <p>16 think that the most prevalent form of loading would</p> <p>17 make that mode the most likely. So those are the</p> <p>18 three -- I mean, those are the three sort of broad</p> <p>19 classifications of how the arms failed.</p> <p>20 Q. Okay. I want to be sure that I understand</p> <p>21 these numbers. You say you had six fractured recovery</p> <p>22 filters, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And I understand that these numbers wouldn't</p> <p>25 add up to six, because you are looking at individual</p>	<p>1 there are one, two, three, four, five arms that failed</p> <p>2 at the rim where the crack propagated inward, which is</p> <p>3 an unusual -- I mean, based on what you think the</p> <p>4 loading is, it is a bit unusual. And two of those you</p> <p>5 can -- the crack initiates right where the wire is at</p> <p>6 the rim.</p> <p>7 The other two, it is slightly displaced, you</p> <p>8 know, by a fraction of a millimeter from that point.</p> <p>9 So it is a little bit more difficult to -- but there is</p> <p>10 certainly five examples where the crack grows from the</p> <p>11 rim contact inwards. And the remaining failures --</p> <p>12 Q. Let me back up there, Doctor. I am confused.</p> <p>13 A. It is easy to get confused.</p> <p>14 Q. You told me a moment ago that the crack -- you</p> <p>15 saw two instances -- two arms where the crack initiated</p> <p>16 right at the rim, at the edge of the sleeve. Now you</p> <p>17 are saying five?</p> <p>18 A. Yes, because there are five -- I tried to</p> <p>19 explain that, if you listen to what I said. Two of</p> <p>20 those failures initiated exactly at the rim. The other</p> <p>21 three are slightly displaced, but in all cases the</p> <p>22 crack propagates from the outside of the filter</p> <p>23 inwards.</p> <p>24 Q. So there are two that initiate right at where</p> <p>25 the rim of the sleeve --</p>

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<p>1 A. Contacts, yes.</p> <p>2 Q. -- contacts the wire. And then there are</p> <p>3 three more that do slightly lower from there?</p> <p>4 A. Yeah, yeah. Now, the reason this is important</p> <p>5 is because, you know, it is possible that the wires can</p> <p>6 pull slightly because of their contact with the vessel</p> <p>7 walls. And so, you know, we are looking at it after</p> <p>8 the fact. But there are five total where the cracks</p> <p>9 propagate from the rim contact area in the general</p> <p>10 vicinity inwards.</p> <p>11 And all of the remaining ones, as far as I can</p> <p>12 make out, propagate in the other way. They propagate</p> <p>13 from the inside of the filter, at least the wire</p> <p>14 sections on the inside of the filter, outwards.</p> <p>15 Q. So I am counting 12 total arm fractures on the</p> <p>16 recovery filters.</p> <p>17 A. Well, your expert got it wrong, by the way, on</p> <p>18 two counts. But I count four, five, six, seven, eight,</p> <p>19 nine, ten, eleven, twelve, thirteen, fourteen, fifteen</p> <p>20 arm failures.</p> <p>21 Q. On the recovery filters?</p> <p>22 A. On the recovery filters.</p> <p>23 Q. I am missing three. You told me that there</p> <p>24 were two that you associated with the surface gouge,</p> <p>25 five total that were near the sleeve, two right at the</p>	<p>1 least some of these things are not -- some of them can</p> <p>2 be in more than one category. Two initiated, in my</p> <p>3 opinion, directly from defects, and as such, propagated</p> <p>4 from the rim -- sorry, they are defects. I find that</p> <p>5 five initiated at or near the rim. You are quite</p> <p>6 correct about that.</p> <p>7 And now we are looking at the propagation of</p> <p>8 which way the crack propagated. I can't -- two, three,</p> <p>9 four, five propagated from the outside of the filter</p> <p>10 inwards from the rim contact area, and two, three,</p> <p>11 four, five, six, seven, eight propagated from the</p> <p>12 inside out. And if there is any discrepancy of the</p> <p>13 other ones, I wasn't quite certain.</p> <p>14 Q. So there was eight that propagated inward to</p> <p>15 outward?</p> <p>16 MS. HELM: We have 20?</p> <p>17 MR. NORTH: These numbers are just not adding</p> <p>18 up at all.</p> <p>19 THE DEPONENT: They don't add up because some</p> <p>20 of them initiate at the rim and initiate from the</p> <p>21 outside to the in.</p> <p>22 BY MR. NORTH</p> <p>23 Q. Well, that is the five, right? Five were at</p> <p>24 or near the rim and you said initiated on the --</p> <p>25 A. Okay. I am going to reiterate this again,</p>
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<p>1 rim of the sleeve, and three nearby. So that is seven</p> <p>2 there. And then five where the crack initiated on the</p> <p>3 inside of the wire and propagated outwards.</p> <p>4 A. Yes.</p> <p>5 Q. So where are the other three?</p> <p>6 A. Well, some of them are heavily abraded, so it</p> <p>7 is difficult to be certain what happened. If you look</p> <p>8 at some of the surfaces, they are very badly abraded,</p> <p>9 which is possibly associated -- that could have</p> <p>10 occurred in service when the thing breaks and they rub</p> <p>11 together, or it could have occurred during explant.</p> <p>12 But it is difficult to say exactly how those initiate.</p> <p>13 Q. So if I understand, the three that were badly</p> <p>14 abraded, you just can't tell what was the cause of the</p> <p>15 crack initiation there?</p> <p>16 A. It's certainly fatigue, but I can't really</p> <p>17 tell which were initiating.</p> <p>18 Q. Okay. So what we basically have is two you</p> <p>19 associate with the surface gouge, five near the sleeve,</p> <p>20 two right at the sleeve, and three a little further</p> <p>21 away, five that have the crack initiating on the inside</p> <p>22 and propagating outward, and three unknown.</p> <p>23 A. Let me just reiterate exactly what I am saying</p> <p>24 here so we can then get the record straight. There</p> <p>25 were two that initiated at defects. By the way, at</p>	<p>1 okay? So let's go through this one by one.</p> <p>2 MR. HARTLEY: Some of them are in more than</p> <p>3 one category.</p> <p>4 THE DEPONENT: In more than one category. The</p> <p>5 point is, that some initiate at the rim and also</p> <p>6 initiate from out to in. They are not mutually</p> <p>7 exclusive categories. Simple as that. We can provide</p> <p>8 you with this information and you can look at it at</p> <p>9 your pleasure.</p> <p>10 BY MR. NORTH</p> <p>11 Q. We're going to have to go through this today,</p> <p>12 and we are going to have to have the record straight.</p> <p>13 You told me earlier that in Category No. 2, at or near</p> <p>14 the rim, that those all occurred outward and then</p> <p>15 propagated inward. You said that earlier.</p> <p>16 MR. HARTLEY: Why don't we do this? Let's</p> <p>17 make a copy of his little cheat-sheet, and then he can</p> <p>18 tell you what he's got on his cheat-sheet so you can</p> <p>19 appreciate what he is talking about. That might help.</p> <p>20 MR. NORTH: Yeah.</p> <p>21 MR. HARTLEY: Because I know -- looking over</p> <p>22 his shoulder, he's got like six categories going across</p> <p>23 the top, and some of them have more than one in each</p> <p>24 category.</p> <p>25 MR. NORTH: I understand that. Let's mark</p>

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<p>1 this as Exhibit 7, if we can.  2 (Whereupon Defendants' Exhibit No.  3 7 was marked for identification.)  4 BY MR. NORTH:  5 Q. Okay. We have just marked what we called  6 earlier your crib sheet as Exhibit 7.  7 A. Yes.  8 Q. Okay. I want to understand everything this is  9 telling me. On the left, the first column down, is the  10 filter. And you have the name of the individual filter  11 or plaintiff involving that filter, correct?  12 A. Yes. Yes.  13 Q. The second column has an "R" if it is a  14 recovery filter and a "G2" if it is a G2 filter?  15 A. Correct.  16 Q. Okay. What's No. 3?  17 A. The next column refers to how many arms failed  18 by fatigue.  19 Q. Just arms, not legs, right?  20 A. The last column refers to the legs.  21 Q. Okay. After the column that "Arms Failed by  22 Fatigue," what is the next one?  23 A. The next column refers to the number of arms  24 that I can definitively say propagated from the outside  25 of the arm. And that is -- in the vicinity where the</p>	<p>1 THE DEPONENT: Yeah, where the bend is.  2 BY MR. NORTH  3 Q. Below the sleeve?  4 A. Yeah. Let me just -- that looks like a funny  5 number. Let me have a quick look at that. It is in  6 the region where the wire starts to bend. And so these  7 categories are not mutually exclusive. The first three  8 refer to the direction; the second three refer to where  9 it initiates. And so there is a number of failures in  10 that location, as I have indicated.  11 And then the last one is where it -- where you  12 can attribute the initiation of the crack directly to a  13 surface defect. And I put one as a question mark  14 because that was the one that was indicated by your  15 expert, initiating at an inclusion. And that is  16 exactly -- that is the one that is exactly at the rim,  17 by the way.  18 And the last column refers to the number of  19 feet that failed. And I put -- 1F means a foot, and 1L  20 would mean a leg, because some of the failures didn't  21 occur in the feet. They occurred in the legs. And  22 there are notes in the last column which indicates  23 whether the surfaces were abraded, whether some of the  24 arms or the feet were clipped.  25 Q. Okay. Tell me what it says by "Gray," under</p>
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<p>1 arm is close to the rim, the corner of the rim inwards  2 towards the center of the device.  3 The next column says "in to out," and that  4 says that that's where the fatigue crack that I can see  5 that is not abraded propagates and initiates from the  6 inside of the filter and then propagates out towards  7 the sheath. The remaining columns refer to -- so those  8 two columns refer to the direction in which the crack  9 propagates.  10 Q. I am with you. What's the next one?  11 A. The last three columns refer to where I think  12 the crack initiated from the base of the fractography,  13 and the first of them indicates that it initiates at or  14 in the near vicinity of the rim, and maybe it doesn't  15 come out, but I actually circled two of those, which is  16 the Gray and the Lynch filters where it initiates  17 exactly at the rim, where the contact of the rim is.  18 The next column refers to -- I said a quarter  19 to a half a millimeter below the rim, and that is  20 generally in the region where the bend in the wire is.  21 That's another prime location.  22 Q. Give me that measurement again.  23 A. It is about a quarter to a half a millimeter,  24 and it is generally where that --  25 MR. HARTLEY: That is below.</p>	<p>1 the "Notes" column.  2 A. It says, "clipped one arm and four feet," and  3 the last thing it says is "initiated a gouge."  4 Q. Okay. By "Lindsay," it says "abraded,"  5 correct?  6 A. Yes, some of those were abraded, correct.  7 Q. What does "Lynch" say?  8 A. That says, "inclusion," question mark.  9 Q. Newton says, "clipped, five feet at gouge."  10 A. No. No. The -- yeah, sorry. It is my  11 terminology, but the "clipped, five feet" is separate,  12 and then that particular -- one of those arms failed at  13 a surface gouge.  14 Q. So then under "Stahl," it says two were  15 abraded, correct?  16 A. Yes. Yes.  17 Q. So as I am reading this, because I am looking  18 at the second -- the third column, which is the number  19 of arms that failed, that shows us 15 total arms  20 fractured in the six recovery filters, right?  21 A. Yes.  22 Q. Where do you get the total number -- you told  23 us earlier that three arms were abraded. Where do you  24 get that number?  25 A. Well, I -- one of the Lindsay arms was heavily</p>

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<p>1 abraded, and at least two of the Stahl arms was heavily 2 abraded.</p> <p>3 Q. Okay. So if they are listed as abraded, they 4 are probably not entered in one of these columns over 5 here, correct?</p> <p>6 A. Yeah. Certainly in the Stahl case; I am not 7 certain of the Lynch. I will have to look at the Lynch 8 again -- sorry, I mean the Lindsay case. I think they 9 were included in the columns.</p> <p>10 Q. Yeah. I think you are right; they were 11 included in these columns, still. Okay.</p> <p>12 A. But certainly there is two of the Stahl arms 13 that are so badly abraded, I can't really tell where 14 they initiated.</p> <p>15 Q. So out of the 15 fractured arms, there are 16 only five arms you saw that had fractured at or near 17 the contact point between the arm and the sleeve, 18 correct?</p> <p>19 A. That's what I think, yes.</p> <p>20 Q. And only two of those had actually fractured 21 at that point. Three of them were a little bit 22 distance away?</p> <p>23 A. I am not sure I like the word "only," but yes, 24 you are right.</p> <p>25 Q. And you would not associate those that you saw</p>	<p>1 about the chamfer issue, and your opinion that the edge 2 of that sleeve, the rim of the sleeve, is too sharp, 3 correct?</p> <p>4 A. Oh, yes.</p> <p>5 Q. That is true, correct?</p> <p>6 A. Yes. Absolutely.</p> <p>7 Q. Well, what I am saying is, those filters that 8 fractured a quarter to a half a millimeter below that 9 sleeve rim would not be attributable to the sharpness 10 of that sleeve rim, would it?</p> <p>11 A. Well, I haven't done the precise stress 12 analysis, so I don't quite know how much of an effect 13 that chamfer would have beyond the immediate vicinity 14 I suspect you need to talk to Professors Begley or 15 McMeeking about that point.</p> <p>16 Q. So that is outside of the scope of your 17 opinion here to say that?</p> <p>18 A. I am not -- without having that knowledge, I 19 would think that the failures that are occurring, 20 fractures of a millimeter away from the contact point, 21 would be less likely associated with that.</p> <p>22 Q. Right.</p> <p>23 A. But I don't know for certain, no.</p> <p>24 Q. And only as I am reading your chart, two of 25 the 15 fractured arms in the recovery filters you</p>
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<p>1 that had fractured a quarter to a half a millimeter 2 below the sleeve as having a crack initiation related 3 to that contact point with the sleeve, would you?</p> <p>4 A. Well, it is difficult to tell, because there 5 is a possibility of tension in these arms that pulls 6 them away. So you know, it is a somewhat unusual 7 failure mode to come from the outside to the in, 8 because these arms are being bent in the other 9 direction. So it is -- you can't say with absolute 10 definity that the contact point with the rim is not 11 important there. It's clearly important in two of the 12 cases, and it is a little bit more difficult to be 13 definitive in the other cases.</p> <p>14 Q. I am talking about the ones under the column 15 "a quarter to a half a millimeter below the sleeve."</p> <p>16 A. Oh, I'm sorry.</p> <p>17 Q. That would not be related to that contact 18 point necessarily, would it?</p> <p>19 A. Well, it is difficult to say, because, you 20 know, the contact point there could raise the overall 21 stresses, but I would have thought that it would be 22 less likely there. It is more -- it seems to be 23 associated with the bend in the arm rather than the 24 contact point.</p> <p>25 Q. Well, we are going to talk in a little while</p>	<p>1 would, yourself, attribute to surface gouges?</p> <p>2 A. Yes.</p> <p>3 Q. And you said earlier that it was unusual, in 4 your view, to see the crack beginning on the outside of 5 the filter arm and propagating to the inside?</p> <p>6 A. Well, just from a rudimentary understanding of 7 how these filters would be loaded in practice, which is 8 the arms would tend to bend out. So, you know, at 9 first sight you would correct the cracks to go from the 10 inside to the outside. So it was -- I must say, I was 11 a little surprised to see the cracks going the other 12 direction initially.</p> <p>13 Q. Well, out of the 15 cracks, or 15 fractures, 14 only five of them showed that phenomenon where the 15 crack began on the outside and moved inside, correct?</p> <p>16 A. Thirty percent. That is a lot of them.</p> <p>17 Q. That wasn't my question. My question was, 5 18 of 15 showed that phenomenon, the crack starting on the 19 outside and moving to the inside, correct?</p> <p>20 A. Yes.</p> <p>21 Q. I'm sorry?</p> <p>22 A. Yes, absolutely. I was a little surprised by 23 that.</p> <p>24 Q. And eight of them, you show that the crack 25 began on the inside and propagated to the outside,</p>

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<p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And so obviously eight and five adds up to</p> <p>4 thirteen. And that is two less than the number of</p> <p>5 fractured arms we had. So I am assuming that with two</p> <p>6 of the abraded arms, you could not tell where the crack</p> <p>7 began; is that correct?</p> <p>8 A. Yes.</p> <p>9 Q. And it looks like that would be two of the</p> <p>10 Stahl arms that you couldn't tell where it began?</p> <p>11 A. Yes.</p> <p>12 Q. So you saw a total of four --</p> <p>13 A. Yes, that is right.</p> <p>14 Q. -- but you only have two listed under those</p> <p>15 two columns, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And even though one of the Lindsay arms was</p> <p>18 abraded, you were able to tell that both of those began</p> <p>19 with an inside crack that propagated to the outside,</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 Q. Now, with those arms that fractured, because</p> <p>23 the crack began on the inside and moved to the outside,</p> <p>24 you did not associate those cracks with any surface</p> <p>25 irregularities on the wire, correct?</p>	<p>1 Q. Well, let me ask you this: If one of these</p> <p>2 arms on this filter got bent at least partially</p> <p>3 upwards, and then was bent back and forth over time,</p> <p>4 like a paper clip bending back and forth, what type of</p> <p>5 crack would that show as far as starting inside going</p> <p>6 to the outside or starting outside going to the inside?</p> <p>7 A. Well, it is in bending and therefore on one</p> <p>8 side it would be tensile; the other side would be</p> <p>9 compressive. It would depends on --</p> <p>10 THE REPORTER: In one side it would be what?</p> <p>11 THE DEPONENT: Would be tensile, the other</p> <p>12 side would be compressive. It would depend on</p> <p>13 precisely the relative magnitude of those two</p> <p>14 conditions. I mean, you can bend something -- you</p> <p>15 know, it depends on the relative magnitude to this. So</p> <p>16 the cracks generally proceed under tensile, not</p> <p>17 compressive stresses. So whatever would seize the</p> <p>18 tensile stress would be the one that would initiate the</p> <p>19 crack. And all of that could be perturbed by the</p> <p>20 fact that there is some imperfection on the surface.</p> <p>21 That could be the trigger to initiate the crack.</p> <p>22 BY MR. NORTH</p> <p>23 Q. So --</p> <p>24 A. Let me just finish. I think if you refer to</p> <p>25 the fact where the arms may have perforated the vessel</p>
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<p>1 A. I wasn't able to associate that. I mean,</p> <p>2 there is -- generally, cracks begin at surface</p> <p>3 irregularities and/or where there is rubbing or</p> <p>4 fretting. So when they propagate from the inside to</p> <p>5 the out, they are in contact with other wire. It is a</p> <p>6 little difficult to see because you can't look at the</p> <p>7 surface of the wire anymore. So I -- I was unable to</p> <p>8 relate those to a specific surface defect or surface</p> <p>9 imperfection.</p> <p>10 Q. Now, this is going to be a very stupid</p> <p>11 question from somebody that does not have your</p> <p>12 training. When you are talking about a crack that</p> <p>13 begins on the inside and propagates to the outside, you</p> <p>14 mean inside the core of the wire?</p> <p>15 A. No, I don't.</p> <p>16 Q. Or do you mean -- that's why I want to see.</p> <p>17 Are you talking about if you have the filter, are you</p> <p>18 talking about one that begins on the side of the arm</p> <p>19 closer to the center point of the filter and moves</p> <p>20 outward?</p> <p>21 A. Yes.</p> <p>22 Q. Okay, good. Now, have you heard or seen</p> <p>23 anything in the documents you reviewed about something</p> <p>24 called the "saluting arm phenomenon"?</p> <p>25 A. I don't recall that, no.</p>	<p>1 or they were stuck to the vessel, my feeling would be</p> <p>2 under those sort of conditions that the maximum tensile</p> <p>3 stresses would be such that the crack would go from the</p> <p>4 inside of the filter to the outside. I think that</p> <p>5 would be the more likely scenario there.</p> <p>6 Q. Let's talk about the feet and legs.</p> <p>7 A. Sure.</p> <p>8 Q. On the recovery filters -- if Mr. Hartley</p> <p>9 would quit laughing at my --</p> <p>10 MR. HARTLEY: It was the tone.</p> <p>11 BY MR. NORTH</p> <p>12 Q. You only identified one fractured leg in all</p> <p>13 the six recovery -- explanted recovery filters,</p> <p>14 correct, leg as opposed to foot?</p> <p>15 A. In the recovery, yeah, there was one failure</p> <p>16 where it sort of -- it fractured in the leg, at sort of</p> <p>17 half length.</p> <p>18 Q. And the rest were in the foot. And that would</p> <p>19 be right around the small little curved hook area,</p> <p>20 correct?</p> <p>21 A. That is right, yes.</p> <p>22 Q. And isn't it your understanding that when this</p> <p>23 filter is implanted, it is released from a cone where</p> <p>24 the Nitinol is compressed, and it springs out to its</p> <p>25 original shape?</p>

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<p>1 A. Yes.</p> <p>2 Q. And then these hooks or feet touch, ideally,</p> <p>3 the circumference of the inferior vena cava?</p> <p>4 A. Correct.</p> <p>5 Q. And are you aware of the fact that over time,</p> <p>6 they incorporate themselves into the tissue?</p> <p>7 A. I would imagine it would, yes.</p> <p>8 Q. And then if they are explanted and removed, a</p> <p>9 device comes down over the top of the filter and</p> <p>10 collapses it, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And it removes the feet from the wall of the</p> <p>13 inferior vena cava?</p> <p>14 A. Correct.</p> <p>15 Q. And therefore it is entirely possible that</p> <p>16 these fractured feet or these feet that you observed,</p> <p>17 fractured during the retrieval processes, correct?</p> <p>18 A. Incorrect.</p> <p>19 Q. Why is that?</p> <p>20 A. Because they are fatigue failures, so possibly</p> <p>21 the final separation of the feet occurred during the</p> <p>22 extraction. But they certainly have fatigue --</p> <p>23 evidence of fatigue in them. So those fractures had to</p> <p>24 have occurred in situ. Fatigue is a process that takes</p> <p>25 place over time in a number of cycles. So typically</p>	<p>1 I wouldn't know the answer to that question.</p> <p>2 Q. Okay. And this also includes your findings</p> <p>3 regarding the G2 filters, correct?</p> <p>4 A. It does contain those, yes.</p> <p>5 Q. And I suspect we will ask you about those in</p> <p>6 the future.</p> <p>7 A. At some later date, yes.</p> <p>8 Q. In one of the filters you received back, there</p> <p>9 is no evidence of fracture; is that correct?</p> <p>10 A. In the case of the G2, it is not in</p> <p>11 recoveries. Only one filter seemed to have no failures</p> <p>12 at all.</p> <p>13 Q. I believe that you determined that the</p> <p>14 fractures you saw resulted from cyclic fatigue?</p> <p>15 A. They -- apart from the ones that were abraded</p> <p>16 where it is difficult to say, they were all associated</p> <p>17 with fatigue.</p> <p>18 Q. And I believe you found that the crack had to</p> <p>19 initiate and then move -- propagate between 33 and</p> <p>20 50 percent through the cross-section of the wire before</p> <p>21 the fracture would actually occur?</p> <p>22 A. Yeah, that's what it looks like, yes.</p> <p>23 Q. Is that figure, 33 to 50 percent, generally</p> <p>24 standard for materials like this?</p> <p>25 A. It depends on the loading. The higher the</p>
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<p>1 those feet failed by about half of the fracture</p> <p>2 surfaces fatigue, or something like that.</p> <p>3 And the rest is what is called overload</p> <p>4 failure where it finally snaps. Difficult to be</p> <p>5 certain when it finally snapped. It could have snapped</p> <p>6 in service; it could have snapped during explantation.</p> <p>7 But the fatigue process, the fact that the foot was</p> <p>8 cracked halfway through, had to have occurred in</p> <p>9 service, had to have occurred in service.</p> <p>10 Q. You haven't reviewed the medical records of</p> <p>11 any of these plaintiffs, have you?</p> <p>12 A. No.</p> <p>13 Q. You haven't reviewed their depositions, have</p> <p>14 you?</p> <p>15 A. No.</p> <p>16 Q. As you sit here today, are you aware of any</p> <p>17 plaintiff in which a fractured foot of a filter, as</p> <p>18 opposed to a fractured arm or leg, has caused any</p> <p>19 physical injury?</p> <p>20 A. Would you repeat the question?</p> <p>21 Q. As you sit here today, are you aware of any</p> <p>22 plaintiff in this litigation who had a fractured foot</p> <p>23 where that fractured foot, as opposed to a leg or an</p> <p>24 arm in the filter, caused a physical injury?</p> <p>25 A. I haven't reviewed the patient information, so</p>	<p>1 loading, you know -- the crack would transition from a</p> <p>2 fatigue crack to an overload crack when the loads</p> <p>3 exceed the so-called fracture strengths. And as the</p> <p>4 fatigue crack propagates, the remaining load-bearing</p> <p>5 region is getting small, and so the point at which it</p> <p>6 fails, separates into two pieces, is a function not</p> <p>7 simply of the material but of the particular loads or</p> <p>8 stresses that it is seeing, or, you know, as we talk</p> <p>9 about the feet, some of those fractures of the feet</p> <p>10 could have occurred during explant. But they were</p> <p>11 certainly cracked halfway through.</p> <p>12 Q. Well, I mean, in your studies, have you seen</p> <p>13 other applications where Nitinol might crack before the</p> <p>14 crack propagates 30 percent of the -- wire?</p> <p>15 A. All devices, you know, whether you are talking</p> <p>16 about aerospace or medical devices, one of the</p> <p>17 principal modes of failure is propagation of fatigue</p> <p>18 cracks. And the fatigue cracks will propagate what is</p> <p>19 called sub-critically at a stress less than the</p> <p>20 fracture stress. As it propagates, the remaining area</p> <p>21 becomes smaller and smaller and smaller, and eventually</p> <p>22 the part will presumably fail.</p> <p>23 And so depending on the geometry of the part</p> <p>24 or the loads it experiences, the amount of fatigue</p> <p>25 prior to the fracture can be in some cases 1 percent,</p>

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<p>1 2 percent, 10 percent, 99 percent. So, you know, 30 to 2 50 percent is not atypical. But you can't generalize 3 like that. 4 MR. NORTH: Why don't we take lunch? 5 THE VIDEOGRAPHER: Video going off the record. 6 The time on the monitor is 12:23 p.m. 7 (Off the record from 12:23 p.m. 8 to 1:26 p.m.) 9 THE VIDEOGRAPHER: Coming back on the record, 10 the time on the monitor is 1:26 p.m. Please begin. 11 BY MR. NORTH 12 Q. Dr. Ritchie, a few questions and then we'll 13 continue into the course of this. What is your 14 understanding of where in the human body the inferior 15 vena cava is located? 16 A. It sits in the artery to the lung. It leads 17 to the artery to the lung. 18 Q. Are there any other veins that feed into it, 19 to your knowledge? 20 A. I am sure there is. 21 Q. So you are not -- you're not that familiar 22 with the details of the anatomy in that area? 23 A. No. 24 Q. I believe you mentioned in the answer to some 25 of the previous questions that seeing the crack</p>	<p>1 generalization. It is difficult to say. 2 Q. So it could be either way? 3 A. It could be either way. I mean, in the 4 general sense, it could be either way. 5 Q. Did I understand you to use a word 6 "perturbated" or something like that earlier? 7 A. I don't know. 8 Q. Okay. Now, I believe you testified earlier 9 that you were believing a likely scenario for the 10 cracks that initiated on the inside and then propagated 11 to the outside of the arms, was a situation where the 12 arms were adjoined to the IVC wall? 13 A. That's one possibility, yes. 14 Q. And how would the forces operate there to 15 cause a crack initiation and propagation in that 16 sequence? 17 A. Well, it depends on the -- exactly how it 18 adheres to the wall, but the reality is, you have a 19 variety of different loading modes on these things. 20 You have blood flow, and you've got clots hitting, and 21 you've got the possibilities if these things impact on 22 the wall. The wall is moving, and there is motion, 23 perhaps this way, so a variety of different loading 24 modes can happen that way, and they tend to be cyclic. 25 So, again, it is difficult to be precise about</p>
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<p>1 initiate on the outside of the arm and then propagate 2 inside was an unusual finding? 3 A. Yes. When I -- it was somewhat unexpected to 4 me. I would have thought they would have propagated in 5 the other direction. 6 Q. Can you explain why that was unexpected? 7 A. You have basically got a filter, and the 8 loading tends to move the arms out. And if -- so you 9 expect mainly the cracks to initiate outward towards 10 the edge of the filter. Of course, it is pulsatile 11 loading, so it is cyclic, as you mentioned yourself. 12 There is always a possibility it may go either way, but 13 I -- my first inkling is I expect to see them in the 14 other direction. 15 Q. If you saw an arm that cracked right next to 16 the rim of the sleeve -- 17 A. Yes. 18 Q. -- as you did in that leads to -- right there 19 at the rim? 20 A. Yes. 21 Q. Would you expect the pressure point between 22 that rim of the sleeve and the wire to cause the crack 23 to initiate on the inside or the outside of the wire? 24 A. Depends on how it is loaded. Again, it's 25 where the tensile stresses are. So, again, it's a</p>	<p>1 where you would expect it, but just from a simple 2 application, if it is bending this way, you might 3 expect to cracks to be here and be going that way. 4 Again, all of this is -- can be changed by the nature 5 of the surface conditions or the details there. 6 I mean, cracks propagate, initiate and 7 propagate when they see a certain level of stress, and 8 that stress can come from the global stress associated 9 with the loading that it sees, but also come about due 10 to the local stresses associated with imperfections, 11 design defects, or design that can locally elevate the 12 stresses. 13 MR. NORTH: In looking through your billing 14 records -- and we would like to have these marked as 15 the next exhibit. We'll mark the outside and then have 16 a duplicate copy of this CD made. 17 (Whereupon Defendants' Exhibit No. 18 8 was marked for identification.) 19 BY MR. NORTH 20 Q. Okay. What we've marked as Exhibit 8, is that 21 a CD that contains your billing records? 22 A. Yes. 23 Q. In looking through those billing records, we 24 noticed that there was a great deal of activity in 25 2009. Is that when you received the filters to</p>

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<p>1 examine?</p> <p>2 A. I got most of them then. I think I got all</p> <p>3 but perhaps three or four at that point.</p> <p>4 Q. And then we didn't see, virtually, any</p> <p>5 activity in 2010. And why is that?</p> <p>6 A. I don't think there was any activity in</p> <p>7 2000 --possibly -- I don't think I missed my billing</p> <p>8 records, but certainly there was a large degree of</p> <p>9 activity when we first got the filters to look at.</p> <p>10 There was activity during the time I wrote the reports.</p> <p>11 Q. And that would be in 2011 when you wrote the</p> <p>12 reports, correct?</p> <p>13 A. Well, I wrote earlier versions of them. So it</p> <p>14 was an earlier version written -- I wrote a report as I</p> <p>15 first did the analysis. And then I -- and I billed --</p> <p>16 I mean, the billings in 2011 were early in 2011 and</p> <p>17 included a lot of activity in the fall of 2010. I</p> <p>18 don't necessarily bill every month.</p> <p>19 So I think most of the activity would have</p> <p>20 been probably in 2009 when we initially looked at most</p> <p>21 of the devices. There was activity in the latter part</p> <p>22 of 2010 when I prepared a report on this. And then</p> <p>23 there would have been activity this year when I revised</p> <p>24 the report to take into account some of these</p> <p>25 additional filters that were sent to me.</p>	<p>1 any filters that had been -- in looking at any filters</p> <p>2 that arrived since September of 2010?</p> <p>3 A. Yes.</p> <p>4 Q. Did Mr. Launey leave at the same time that</p> <p>5 Mr. Gludovatz started?</p> <p>6 A. No. Launey left -- his wife had a baby, so he</p> <p>7 was gone in probably May last year. And Gludovatz</p> <p>8 started in September or October this year. No, maybe</p> <p>9 late November. I can't remember exactly, last year.</p> <p>10 Q. Now, we have marked as Exhibit 7 your chart</p> <p>11 showing the various attributes of each fractured arm --</p> <p>12 A. Yes.</p> <p>13 Q. -- on the recovery filters, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Now, there were two or three plaintiffs in</p> <p>16 this litigation for which you were unable to look at an</p> <p>17 explanted filter, correct?</p> <p>18 A. Yes.</p> <p>19 Q. That is because the filter remains implanted</p> <p>20 in those people, correct?</p> <p>21 A. That is my understanding, yes.</p> <p>22 Q. For those plaintiffs whose filters still</p> <p>23 remain implanted, are you able to say under which</p> <p>24 categories the fractured arms and/or legs of their</p> <p>25 filters would fall?</p>
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<p>1 Q. When is the first time you ever met Mr. Davis</p> <p>2 or Mr. Hartley in person?</p> <p>3 A. I never met Mr. Davis, and I met Mr. Hartley</p> <p>4 for the first time last night.</p> <p>5 Q. Okay. Your billing records -- and this was</p> <p>6 just a quick estimate by my colleague, Ms. Helm --</p> <p>7 appear to total something in the range of 71, 72</p> <p>8 thousand. Does that sound about right, so far?</p> <p>9 A. I have no idea. Quite possible, it is over</p> <p>10 two years, so two or three years.</p> <p>11 Q. So whatever is depicted on Exhibit 8 would be</p> <p>12 an accurate compilation of your billing?</p> <p>13 A. I think so. I couldn't find any other bills</p> <p>14 when I looked last night.</p> <p>15 Q. Mr. Launey, does he still work for you?</p> <p>16 A. No.</p> <p>17 Q. When did he leave your supervision?</p> <p>18 A. I think about this time last year.</p> <p>19 Q. And when did Mr. Gludovatz begin work for you?</p> <p>20 A. In September of last year.</p> <p>21 Q. So Mr. Launey is the gentleman that would have</p> <p>22 been involved working with you in the review of the</p> <p>23 filters in 2009 when they first arrived?</p> <p>24 A. Yes.</p> <p>25 Q. And Mr. Gludovatz would have been involved in</p>	<p>1 A. Of course not.</p> <p>2 Q. So you are unable to say whether there is</p> <p>3 evidence of an association between the surface gouge</p> <p>4 and a crack initiation in any of the filters that still</p> <p>5 remain implanted, correct?</p> <p>6 A. I would imagine that they wouldn't be any</p> <p>7 different in terms of one of those failure modes, but</p> <p>8 with -- certainly without looking at them, I can't say.</p> <p>9 But you can attribute it to any one of those in</p> <p>10 particular.</p> <p>11 Q. Okay. If you would look for a moment at your</p> <p>12 curriculum vitae, on Page 9.</p> <p>13 A. Okay.</p> <p>14 Q. Page 9.</p> <p>15 A. That's what it says here. There is two page</p> <p>16 nines.</p> <p>17 Q. I am looking at the one that has the doctoral</p> <p>18 students graduated.</p> <p>19 A. Okay. Okay. Got you. Right.</p> <p>20 Q. Mr. Launey is not on this one, is he?</p> <p>21 A. No.</p> <p>22 Q. Did he not graduate?</p> <p>23 A. He wasn't a doctoral student.</p> <p>24 Q. What was his position?</p> <p>25 A. He was a postgraduate associate.</p>



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<p>1 Q. Postgraduate associate. Are any of these</p> <p>2 students listed on this Page 9 female?</p> <p>3 A. Runciman, Barth, Zimmerman, Ionova-Martin,</p> <p>4 Barney. Do I need to go on?</p> <p>5 Q. That is fine.</p> <p>6 A. Schroeder.</p> <p>7 Q. Okay. Just checking.</p> <p>8 A. Next question?</p> <p>9 Q. Do you believe that electropolishing would</p> <p>10 have had any positive effects on surface gouging?</p> <p>11 A. Yes, I do.</p> <p>12 Q. In what way?</p> <p>13 A. Fatigue is a process where materials fail</p> <p>14 under cyclic loading, and it is in most cases initiated</p> <p>15 at surfaces. And the condition of the surface,</p> <p>16 particularly any imperfections, scratches or what have</p> <p>17 you, are absolutely critical. So there are various</p> <p>18 ways to take care of this. But one of the ways is to</p> <p>19 polish the surface to try to remove as much of the</p> <p>20 imperfection as you can.</p> <p>21 So for this reason, many device manufacturers</p> <p>22 like to electropolish the surfaces of their devices.</p> <p>23 So the process of electropolishing would have helped to</p> <p>24 smooth out the imperfections that are generated by a</p> <p>25 gouge. So I can't see any negative aspects of doing</p>	<p>1 A. They almost certainly did.</p> <p>2 Q. But you can't identify what specific type of</p> <p>3 imperfection might have been at the crack initiation</p> <p>4 site -- let me finish my question, please -- at these</p> <p>5 other fracture points?</p> <p>6 A. There are so many scratches and, you know,</p> <p>7 roughness on that surface that you can't depict an</p> <p>8 individual imperfection. But given the option, the</p> <p>9 fatigue crack would always find the imperfection.</p> <p>10 Q. On Page 13 of your report, you say -- you make</p> <p>11 the following statement, "Most manufacturers of Nitinol</p> <p>12 medical devices choose to polish, or better still,</p> <p>13 electropolish the surface of their components for</p> <p>14 exactly this reason."</p> <p>15 A. I know I said that, yes.</p> <p>16 Q. Okay. So the same sort of effect or</p> <p>17 improvement that you are talking about can be achieved</p> <p>18 with other polishing procedures other than just</p> <p>19 electropolishing?</p> <p>20 A. Mechanical polishing has its drawbacks because</p> <p>21 it can cause damage as well. There is potential</p> <p>22 benefits. It can put residual stresses in, but by and</p> <p>23 large mechanical polishing is a less effective</p> <p>24 technique. Electropolishing requires no mechanical</p> <p>25 abrasion, so to speak.</p>
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<p>1 that, and there would certainly be potential positive</p> <p>2 aspects.</p> <p>3 Q. Now, I understand that in your examination of</p> <p>4 the filters you found surface flaws and irregularities</p> <p>5 in a number of --</p> <p>6 A. Let's call it an imperfection, shall we?</p> <p>7 Q. Imperfections. But in going through the chart</p> <p>8 on Page 7 and discussing that with you, it is my</p> <p>9 understanding that you were only able to associate the</p> <p>10 crack initiation site of a fractured arm with a surface</p> <p>11 imperfection in two of the fractured arms, correct?</p> <p>12 A. Well, there are so many imperfections on the</p> <p>13 surface, it is difficult to be precise, and undoubtedly</p> <p>14 all of these cracks didn't initiate in a perfectly</p> <p>15 smooth region. There are always found some</p> <p>16 imperfection, as every crack does. But certainly with</p> <p>17 regard to the bigger imperfections, the gouges, as I</p> <p>18 have talked about, amongst the recovery filters, two of</p> <p>19 the arms, in my opinion, definitively initiated those</p> <p>20 gouges.</p> <p>21 Q. I understand that is your opinion that some of</p> <p>22 the other fractures probably initiated at locations</p> <p>23 where surface imperfections existed.</p> <p>24 A. I can say they did.</p> <p>25 Q. I'm sorry, what?</p>	<p>1 If you look at the vast majority of components</p> <p>2 that fatigue, and you look at the data that shows what</p> <p>3 the stress is to cause fatigue, generally speaking, the</p> <p>4 electropolished surfaces will always have a higher</p> <p>5 fatigue resistance just because they are removing these</p> <p>6 small defects. And there are other advantages, by the</p> <p>7 way. With Nitinol the electropolishing is also</p> <p>8 associated with setting up a pasible, which is --</p> <p>9 THE REPORTER: Could you repeat that?</p> <p>10 THE DEPONENT: Setting up a pasible,</p> <p>11 p-a-s-i-b-l-e, which is helpful for corrosion</p> <p>12 resistance, and the device looks better as well, which</p> <p>13 is not an unimportant point.</p> <p>14 THE VIDEOGRAPHER: Could you raise that,</p> <p>15 please? We are losing it.</p> <p>16 THE DEPONENT: Sure. Sorry.</p> <p>17 BY BY MR. NORTH:</p> <p>18 Q. During the course of the litigation, have you</p> <p>19 had any discussions with Dr. McMeeking about</p> <p>20 electropolishing?</p> <p>21 A. I don't think so.</p> <p>22 Q. Have you had any discussions with Scott</p> <p>23 Robertson about electropolishing?</p> <p>24 A. I think we talked to him about it, yes.</p> <p>25 Q. With regard to the Bard filters?</p>

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<p>1 A. Yeah, probably in regard to the Bard filters.</p> <p>2 Q. Did Scott Robertson ever actually examine one</p> <p>3 of these filters with you?</p> <p>4 A. I think he examined one of the earlier ones,</p> <p>5 actually. I said this morning, I think that is where</p> <p>6 probably Mr. Hartley and Mr. Davis got my name. I</p> <p>7 mean, he certainly looked at the filters in his paper.</p> <p>8 So I don't know quite which ones he looked at.</p> <p>9 Q. Have you examined any electropolished filters</p> <p>10 as a part of your work in this case?</p> <p>11 A. No.</p> <p>12 Q. Are you aware of whether or not there are any</p> <p>13 electropolished filters on the market?</p> <p>14 A. Yeah, Bard makes one, doesn't it?</p> <p>15 Q. Besides Bard's filter that is electropolished,</p> <p>16 are you aware of any others that are electropolished on</p> <p>17 the market?</p> <p>18 A. I don't know the details of the other filters.</p> <p>19 Q. So you have made no comparative study of the</p> <p>20 polishing procedures or techniques for Bard filters as</p> <p>21 opposed to competitive filters, have you?</p> <p>22 A. No. My opinion is based solely on just a</p> <p>23 general understanding of fatigue and fatigue resistance</p> <p>24 and how, in virtually every case I looked at, the</p> <p>25 electropolished surface has better fatigue resistance</p>	<p>1 there should be no markings at all?</p> <p>2 A. No. That would be impossible, probably, to</p> <p>3 get no markings, but certainly a non-electropolished</p> <p>4 surface would tend to show some of the draw-markings</p> <p>5 that you see. They are not so damaging because they</p> <p>6 tend to be aligned along the wire, rather than</p> <p>7 circumferential. But the gouge marks, I think, are</p> <p>8 much more serious in terms of possibly initiating</p> <p>9 fatigue cracks. And, you know, the nature of the legs</p> <p>10 and particularly the feet, there the grinding marks are</p> <p>11 pretty severe. And they undoubtedly would have</p> <p>12 initiated fatigue cracks down there.</p> <p>13 You know, a lot depends on the nature of the</p> <p>14 device. If the device is highly stressed, then the</p> <p>15 issue of the surface becomes much, much more important</p> <p>16 If the device is not that highly stressed, then it is</p> <p>17 not so important. Because it is the -- it is the</p> <p>18 synergism of the applied stresses and the local stress</p> <p>19 concentrations that leads to the stresses that cause</p> <p>20 failure. If you have a low -- a device that isn't</p> <p>21 stressed very much, then the surface condition becomes</p> <p>22 somewhat less important.</p> <p>23 Q. Are you able to quantify the extent of surface</p> <p>24 markings that you would consider acceptable?</p> <p>25 A. It is a -- it is an almost impossible question</p>
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<p>1 than the non-electropolished surface.</p> <p>2 Q. With regards specifically to inferior vena</p> <p>3 cava filters, you have not done any comparative tests</p> <p>4 between electropolished filters and filters that have</p> <p>5 not been electropolished?</p> <p>6 A. By "tests," you mean by mechanical tests --</p> <p>7 THE REPORTER: I'm sorry. Would everybody</p> <p>8 please slow down so that I can get each speaker</p> <p>9 speaking? Repeat that please. The question was, "With</p> <p>10 regards specifically to inferior vena cava filters, you</p> <p>11 have not done any comparative tests between" -- could</p> <p>12 you finish this question for me please, it went a</p> <p>13 little fast -- "between electropolished" --</p> <p>14 MR. NORTH:</p> <p>15 Q. -- filters and filters that have not been</p> <p>16 electropolished?</p> <p>17 A. As in tests by mechanical filters?</p> <p>18 Q. Yes.</p> <p>19 A. As no, I have not.</p> <p>20 Q. In your report, you state, and I quote, "The</p> <p>21 nature of the surface of the wire arms and legs was</p> <p>22 microscopically very rough."</p> <p>23 A. Yes.</p> <p>24 Q. What condition for the wires would you</p> <p>25 consider acceptable? Is it your expectations that</p>	<p>1 to answer. If you can see if these devices fail, and</p> <p>2 they fail even in small numbers at places where you see</p> <p>3 surface imperfections, then clearly those imperfections</p> <p>4 are not acceptable.</p> <p>5 Q. At one point in your report, you state that</p> <p>6 surface gouges could have been avoided by improved</p> <p>7 manufacturing procedures and/or quality control.</p> <p>8 A. Yes.</p> <p>9 Q. Do you have any specific manufacturing</p> <p>10 procedures or quality control procedures that you</p> <p>11 believe should have been implemented?</p> <p>12 A. They could have looked at them. They could</p> <p>13 have looked at these -- you know, in the heart-valve</p> <p>14 industry, it was my recommendation that every -- every</p> <p>15 valve be examined. And in the case of Shiley, every</p> <p>16 valve was put into a scanning electron microscope. I</p> <p>17 get the impression reading the depositions that these</p> <p>18 things weren't looked at.</p> <p>19 As regard manufacturing procedures, certainly</p> <p>20 shape-setting shouldn't involve big gouges on the</p> <p>21 surface. I mean, that should be avoided, and it seems</p> <p>22 like there is far less evidence in the G2, so I presume</p> <p>23 that Bard found a way to avoid that. But they are</p> <p>24 highly undesirable.</p> <p>25 Q. So it is your impression that these filters</p>

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<p>1 are not individually examined as a part of the 2 manufacturing process?</p> <p>3 A. Depends on when you say "examined." I 4 think -- I mean, a certain percentage should be 5 examined at high magnification to see the nature of the 6 surface. I don't know. There wasn't enough 7 information that I was able to glean about how -- what 8 proportion were examined. I think I remember one 9 deposition from somebody at Bard saying that very few 10 were looked at after manufacturing, but I don't know 11 the details of that. But I think if they were 12 examined, and someone had seen those gouges, then a big 13 red flag should have been raised.</p> <p>14 Q. On the explanted filters, do you believe that 15 some of the markings you saw could have been caused 16 during the retrieval procedure?</p> <p>17 A. Some of the markings, certainly. I mean, the 18 draw-markings that you see are clearly draw-markings. 19 The centralist grinding markings are certainly 20 centralist grinding markings. The gouges -- the other 21 ones that we saw in the exemplar filters clearly would 22 not have been caused by explantation.</p> <p>23 I think some of the abrasions of the fracture 24 surface -- as I said, that could be caused by the two 25 surfaces rubbing together if the thing broke</p>	<p>1 given a shape-setting heat treatment. So you heat it, 2 typically about 500 C, so the structure then forms in 3 that shape, and that's how the material remembers it.</p> <p>4 So it seems to me that because these gouges 5 were generally in the region where there was a bend in 6 the wire, that the most probable way those were put in 7 was during the shape-setting procedure.</p> <p>8 Q. So you just base that observation on the 9 location of the gouge marks on that particular filter?</p> <p>10 A. Well, not totally. I mean, they look like 11 something that was done during the bending procedure. 12 So it is -- put it this way, it is certainly an 13 educated assumption, if that means anything. I am sure 14 they were put in that way, anyway.</p> <p>15 Q. Can you cite to any literature for me that 16 discusses the fatigue resistance of electropolished 17 Nitinol wire as opposed to electropolished Nitinol 18 stents -- or not stents, but electropolished Nitinol 19 tubing?</p> <p>20 A. Yes. There is a paper that your expert 21 pointed out by Patel that does look at that, yes.</p> <p>22 Q. Had you read the Patel article before?</p> <p>23 A. No, I hadn't, actually. It is in a rather 24 obscure place. It isn't in an archival journal, so I 25 hadn't read it before.</p>
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<p>1 prematurely or could have been caused as the thing was 2 explanted. So some damage certainly would be 3 associated with explanting. I think some of the feet 4 that were clipped off, that was probably done during 5 explant. I can't see any reason why it would be done 6 later.</p> <p>7 Q. Would you agree that the exemplar filters you 8 viewed exhibited fewer surface marks than the explanted 9 filters?</p> <p>10 A. I didn't get that impression.</p> <p>11 Q. With regard to the Stahl filter, you made the 12 following comment, that the gouges were presumably 13 formed during manufacture, probably by bending on a 14 mandrel during shape-setting.</p> <p>15 A. Yes.</p> <p>16 Q. How were you able to determine that?</p> <p>17 A. Well, just by my understanding of how these 18 things are made. Most Nitinol devices have to be 19 shape-set, they have to put into a certain shape which 20 then the material remembers. That is the whole point. 21 So you do this by deforming it.</p> <p>22 And a mandrel is used in the general term. I 23 think Bard has some sort of device where they stick the 24 thing in and the wires bend over some section, so it is 25 deformed in that condition. And then it is -- it is</p>	<p>1 Q. Did you read it as a part of your work in this 2 case?</p> <p>3 A. I've read it, yes.</p> <p>4 Q. Did you read it only after you received our 5 expert's report?</p> <p>6 A. Yes.</p> <p>7 Q. And what was your impression of that article?</p> <p>8 A. It was an interesting article. They did a lot 9 of fatigue tests and tried to compare the conditions of 10 electropolished versus mechanically and etched, and so 11 forth.</p> <p>12 Q. Did you disagree with their conclusions?</p> <p>13 A. No. I think -- I mean, it is difficult to 14 disagree with experimental results. So I disagreed 15 with the interpretation that your expert put on them, 16 but I certainly don't disagree with the article.</p> <p>17 MR. NORTH: If we could mark this as the next 18 exhibit.</p> <p>19 (Whereupon Defendants' Exhibit No. 20 9 was marked for identification.)</p> <p>21 BY MR. NORTH</p> <p>22 Q. Let me hand you what's been marked as Exhibit 23 9. Is that the Patel article that we were just 24 referencing?</p> <p>25 A. Yes.</p>



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<p>1 Q. What about the interpretation that my expert 2 placed on this do you disagree with? 3 A. Well, let's read what she said, shall we? 4 Q. Sure. 5 A. She said, "One study by Patel evaluated the 6 surface condition of the laboratory fatigue performance 7 of Nitinol wire" -- 8 THE REPORTER: Please read slowly. 9 THE DEPONENT: You can take it afterwards. 10 THE REPORTER: Would you please read that 11 slowly for me for the record. This is how we have to 12 do it, unfortunately. She said "One study by Patel 13 evaluated the surface condition of" -- 14 THE DEPONENT: -- "the laboratory fatigue 15 performance of" -- 16 THE REPORTER: Slowly and clearly for the 17 record. 18 THE DEPONENT: -- "the laboratory fatigue 19 performance of Nitinol wire. The results of this study 20 found that of the seven surface conditions the fatigue 21 performance of the electropolished wire was fourth of 22 seven. In comparison, the etched surface, which 23 appears to closely compare with the recovery surface, 24 performed the best of the seven finishes in both high 25 and low-cycle fatigue."</p>	<p>1 clean the surface up and if you electropolish the 2 surface, it will have better fatigue reference. 3 You are probably familiar with the Southwest 4 Airline crashes -- not crashes, but they had holes in 5 the fuselage. That was all caused by having too rough 6 a surface around the fastening holes. This is Fatigue 7 101. You want a smooth surface if you want to avoid 8 fatigue problems. 9 Q. Do you not believe that etched surfaces work 10 well also? 11 A. I mean, the difficulty of interpreting this is 12 the fact that sometimes you can put in -- sometimes 13 these things have residual stresses in the surface. So 14 when you etch them or electropolish or do something to 15 them, you can change that. I don't know quite -- I 16 didn't do the study by Patel, so I don't know quite 17 what they looked at. They didn't mention these issues, 18 but these are issues that you have to decide on. 19 But, you know -- if this was a lowly stress 20 device, it wouldn't be so important that the surface 21 was rough. You wouldn't perhaps need to electropolish. 22 But in view of the fact the stresses are so high, I 23 mean... 24 Q. If this filter was electropolished, do you 25 believe that it would prevent all fractures?</p>
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<p>1 BY MR. NORTH 2 Q. What do you disagree with, with that 3 statement? 4 A. Oh, I think the problem with that statement is 5 that I see absolutely no evidence in the -- that I have 6 read, that when dealing with an etched surface here -- 7 this is an oxide surface, not an etched surface, point 8 No. 1. And, secondly, Patel didn't examine Nitinol 9 wire with gouges on it. And thirdly, that if you look 10 at the high -- the high-strain fatigue, that, in fact, 11 the electropolished surface looks pretty good. It 12 looks far better than the oxide surface. 13 Q. Point to me where you are referencing right 14 there. Is that in one of these figures? 15 A. Figure 9. Figure 9. I mean, I -- this 16 surface, to me, looks like a black oxide surface to me, 17 but I am not going to make distinctions between whether 18 it is black or dark, or what have you, but certainly 19 electropolished is second only to the etched surface. 20 So, that is what Patel says, so I think that 21 is a rather judicious interpretation of what Patel 22 said. Secondly, that eventually -- I have had 23 experience in fatigue for 40 years, and in virtually 24 every experience that I've looked at, every bit of data 25 I have looked at, irrespective of the material, if you</p>	<p>1 A. No. No. I think -- I mean, very rarely can 2 you attribute anything to one factor. It is always a 3 multitude of factors. And the fact that there are so 4 many different failure modes here points to several 5 problems. 6 Maybe they all need to occur in concert for 7 something to happen, but certainly these surfaces were 8 particularly rough, in my opinion. The gouges were an 9 unnecessary imperfection, and I have -- you can 10 attribute certainly two of the arm failures to those 11 gouges. And I think anything you could do to avoid 12 that problem, and electropolishing would certainly help 13 in that regard, would be advantageous. And clearly, 14 Bard thinks that way, because they are electropolishing 15 their latest filters. 16 Q. Are you aware of any manufacturer of 17 electropolishing inferior vena cava filters in 2002 18 when the FDA first cleared the recovery filter for 19 commercial sale? 20 A. I don't know. 21 Q. Are you familiar with any manufacturers that 22 electropolished inferior vena cava filters in 2005, 23 when the G2 was first cleared for commercial sale? 24 A. I don't know. They should have done. I don't 25 know.</p>

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1 Q. You would agree that you saw a number of  
2 surface gouges on these explanted filters in which no  
3 crack had initiated, correct?

4 A. Yes. Well, I can't see a crack there, anyway.  
5 So there possibly could be one, but it didn't cause  
6 final failure of the device.

7 Q. Are you familiar with the term "chamfer"?

8 A. Yes.

9 Q. Explain for the record what the chamfer is.

10 A. It is basically the -- it describes the radius  
11 of curvature of, in this case, a corner. And it  
12 pertains to the fact that the sleeve or the rim from  
13 which the arms and the legs emanate from -- the inner  
14 corner of the arms and the legs may actually touch the  
15 sleeve. It is that radius.

16 Q. And what fault or criticism do you have for  
17 the chamfer on the recovery filter?

18 A. Well, it is -- it is a point of stress  
19 concentration, and it is a sharp edge. And there is a  
20 number of problems with this. One is that it could  
21 lead to failures because of the very high stresses.  
22 Bard appears to have noticed this, and on some of their  
23 drawings in the literature that was sent, they call out  
24 for a particular radius. But when we looked at this  
25 they were incredibly sharp -- I mean, incredibly sharp,

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1 I mean, fractions of a human hair sharpness. These are  
2 severely sharp corners.

3 And the difficulty with that is it is very  
4 difficult to calculate the stresses. The stresses can  
5 tend towards infinity there. If it was atomically  
6 sharp, then the stresses would be infinity.

7 So it has two problems. One is it could lead  
8 to a local elevation of stresses which could cause  
9 failure; secondly, it produces a huge uncertainty in  
10 one's ability to calculate the stresses. And that is  
11 bad, too, because knowledge -- computation of the  
12 stresses for a device prior to putting in service is  
13 the most important thing. I mean, in the world of  
14 fatigue, the three most important things are the  
15 stress, the stress, and the stress, and if you can't  
16 calculate them, that puts you at a very severe  
17 disadvantage. That's what I didn't like about that  
18 particular feature.

19 Q. And this chamfer issue relates back to what  
20 you were talking about earlier, about the arms where  
21 they emanate from the sleeves rubbing against the sharp  
22 edge of the rim of the sleeve, correct?

23 A. Yes. That is the location, yes.

24 Q. And that is the one that you have associated  
25 with, two, in your view, definitely where the break

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1 happened right at where the arm comes out the rim, and  
2 three others with regard to the recovery filter where  
3 it was nearby, correct?

4 A. Well, I mean -- certainly there are two that  
5 initiate exactly at the rim.

6 Q. Right.

7 A. There are three others which are close to  
8 there.

9 Q. Right.

10 A. And so -- but there are also a few others  
11 where the cracks are propagating from the outside to  
12 the inside, and so I don't quite know that the -- the  
13 influence of these elevated stresses of the rim would  
14 affect that. It depends on the stress. You have to  
15 ask Begley and McMeeking about that.

16 Q. So from your vantage point, these are the only  
17 five that you think -- that you are able to say, in  
18 your view, may be related to that chamfer point,  
19 correct?

20 A. Yeah. It looks like about 30 percent of the  
21 ones I looked at, yes.

22 Q. Now, I believe you referenced --

23 (Whereupon Defendants' Exhibit No.  
24 10 was marked for identification.)

25 BY MR. NORTH

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1 Q. Let me hand you what's been marked as

2 Exhibit 10. Are these the Bard -- not Bard, but are  
3 these the drawings that you reference in your report as  
4 having called for the chamfer, in your view?

5 A. Yes. They seem to call for the value of the  
6 chamfer. I think this is this same. I, perhaps,  
7 should check.

8 Q. If you would cross-reference that against your  
9 report and double-check that for me so we are clear.

10 A. The Bates numbers would tell us.

11 Q. Yes. I am trying to find the page in your  
12 report where you refer to it.

13 A. I will page number them in the future.

14 Q. Okay. If you look at -- it is right where  
15 these pictures are. The next --

16 A. Yes, that is right.

17 Q. So those are the two drawings you reference in  
18 your report as calling for a chamfer, correct?

19 A. Yeah, they certainly mention the chamfer  
20 specifications.

21 Q. Are there any other materials you saw in the  
22 materials provided to you by Mr. Hartley and Mr. Davis  
23 that called for a chamfer?

24 A. I don't recall, offhand. There might have  
25 been something in the text. This is what caught my

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<p>1 mind. So it is difficult to say all, but I don't think</p> <p>2 so. These are the two engineering drawings that seemed</p> <p>3 to call for the chamfer, yes.</p> <p>4 Q. And these drawings were actually prepared by a</p> <p>5 company called Nitinol Medical Technologies, correct?</p> <p>6 A. That's what it says here, yes.</p> <p>7 Q. Are you aware of the fact that Nitinol Medical</p> <p>8 Technologies originally developed the recovery filter?</p> <p>9 A. I am, indeed.</p> <p>10 Q. And these drawings are dated June 30th of 1997</p> <p>11 and November 24th of 1997, correct?</p> <p>12 A. That's what it says here, yes.</p> <p>13 Q. And were you ever shown later drawings?</p> <p>14 A. No, I wasn't.</p> <p>15 Q. Were you ever shown later specifications for</p> <p>16 the manufacturing of the sleeve?</p> <p>17 A. Not that called out for the chamfer, I think,</p> <p>18 no.</p> <p>19 Q. So these drawings were prepared roughly five</p> <p>20 years before the recovery filter was cleared for</p> <p>21 commercial sale, correct?</p> <p>22 A. That's what it -- yes. 2002, yes.</p> <p>23 Q. And as you sit here today, you don't know</p> <p>24 whether or not the drawings for this device were</p> <p>25 changed or the specifications were altered subsequent</p>	<p>1 surprising. Big ones would be, not small.</p> <p>2 Q. You previously mentioned that the Lynch filter</p> <p>3 was one of the filters that the crack was right at the</p> <p>4 point where the arm and the -- contacted with the rim?</p> <p>5 A. Yes, indeed. Yes.</p> <p>6 Q. Did you see an inclusion at that crack</p> <p>7 initiation?</p> <p>8 A. I didn't. And your expert points one out, and</p> <p>9 it may be right. I mean, to be certain you would need</p> <p>10 to do an EDAX, which is electro-diffraction -- she</p> <p>11 didn't do this either, by the way -- but diffraction to</p> <p>12 see what the composition of that region is. I don't</p> <p>13 think that is an inclusion, but it may be. You know,</p> <p>14 the problem is, that it is occurring right at the point</p> <p>15 where I would expect a fatigue crack to form -- could</p> <p>16 form, and it seems a bit of a coincidence, but it could</p> <p>17 be an inclusion.</p> <p>18 Q. Have you discussed the chamfer issue with</p> <p>19 Dr. McMeeking?</p> <p>20 A. No.</p> <p>21 Q. With Dr. Begley?</p> <p>22 A. Yes.</p> <p>23 Q. So not with Dr. McMeeking, but yes with</p> <p>24 Dr. Begley?</p> <p>25 A. Most of my dealings have been with Dr. Begley.</p>
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<p>1 to 1997, do you?</p> <p>2 A. No. But I know what the reality was on the</p> <p>3 actual part itself.</p> <p>4 Q. Tell me again what an inclusion is.</p> <p>5 A. An inclusion is -- a lot of materials have</p> <p>6 them. It is basically -- it depends what it is. It is</p> <p>7 a little particle. It could be big, of course, but it</p> <p>8 is generally a particle which is associated with</p> <p>9 impurities. So in Nitinol, it can be carbides or</p> <p>10 something like that which can be associated with the</p> <p>11 manufacturing process. In steels you get sulfides</p> <p>12 and -- not carbides, sulfides. And they are little</p> <p>13 particles, and depending on the quality of the</p> <p>14 material. In the case of aircraft quality, you would</p> <p>15 clean the material up as best as you can to limit the</p> <p>16 number of inclusions because they tend to be rather</p> <p>17 brittle, and they can initiate cracks, fatigue cracks.</p> <p>18 Q. It is not unusual to see inclusions that are</p> <p>19 in other material such as Nitinol, at least to some</p> <p>20 extent?</p> <p>21 A. Yeah, you see some inclusions in there.</p> <p>22 Depends on the size. And there are two ways of</p> <p>23 measuring it, and I have forgotten which one, one makes</p> <p>24 somewhat smaller inclusions. But you are right,</p> <p>25 inclusions are certainly not something that would be</p>	<p>1 Q. Why is that?</p> <p>2 A. Just because he is easier to get ahold of.</p> <p>3 Q. Was it you who first raised the issue of</p> <p>4 chamfer with Dr. Begley, or Dr. Begley who first raised</p> <p>5 the issue of chamfer with you?</p> <p>6 A. I can't remember. I think it was probably</p> <p>7 somewhat mutual because I did -- he was in the case a</p> <p>8 lot later than I was, and I had looked and seen these</p> <p>9 failures that occurred near the rim. And then we got</p> <p>10 the papers to -- I don't quite -- I am not quite</p> <p>11 certain exactly where it came from. But it was -- but</p> <p>12 this was something that I thought was important for him</p> <p>13 to do and something related to the stresses involved.</p> <p>14 Q. You would agree that even with the filters you</p> <p>15 examined, they have at least some chamfer or radius of</p> <p>16 curvature, correct?</p> <p>17 A. Oh, yes. It wouldn't be atomically sharp, so</p> <p>18 it has some -- it is pretty sharp.</p> <p>19 Q. So it does have some radius of curvature; it</p> <p>20 just does not have an adequate amount in your view. Is</p> <p>21 that correct?</p> <p>22 A. Well, you know, let me just reiterate. In</p> <p>23 essence, it is true. The point is that the stress</p> <p>24 concentration there is -- is proportional, inversely</p> <p>25 proportional, to that radius of curvature. So if that</p>

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<p>1 radius of curvature is very, very small, stresses get 2 very, very large and vice versa. 3 So generally speaking, one tries to avoid 4 corners in all situations because that reduces the 5 stresses. The original Comet Airlines failed because 6 the windows were square, and they rounded the corners 7 of the windows, and the windows showed fatigue cracks. 8 Generally speaking with all engineering design, when 9 you are worried about fatigue, you remove these 10 corners. And since there was -- and if you evaluate 11 them, and these specifications were changed, then there 12 seem to be no specification for that corner, which 13 means the stresses are sort of unbanded. You can't 14 really calculate them. 15 Q. Did you conduct any testing in an effort to 16 either recreate or to quantify the stresses on the arm 17 at that point of contact with the sleeve rim? 18 A. I am not sure you could do that. 19 Q. So you are not sure you could do that, but you 20 did not do that, did you, is my question? 21 A. No. No. Because I don't think you can do 22 that, actually. 23 Q. Did you conduct any tests to demonstrate that 24 a greater chamfer there would result in less stresses? 25 A. No. It is a no-brainer, but certainly I don't</p>	<p>1 Q. Are you able to say which ones on this list 2 had fretting involved? 3 A. Well, I think, you know, it is -- basically 4 anywhere where you have contacts, and so the ones that 5 were associated with the contacts at the rim, probably 6 fretting was involved there. And then most of them, as 7 you know, are cracks that start from the inside and 8 grow out, and that's where all of the wires are bunched 9 together, and so there is certainly possibly contact 10 there as well. You have a bunch of wires together, so 11 fretting certainly contributed. 12 Q. Your report states the following: "The 13 defective nature of the Bard IVC filters resulted in 14 failure of service because they were inadequately and 15 defectively designed and manufactured to withstand the 16 physiological loading that they experienced in vivo. 17 This appears to be due to an inaccurate evaluation by 18 the manufacturer of the stresses and strains in the 19 device during physiological service." 20 Is that an accurate statement of what you 21 said? 22 A. Yes, indeed. 23 Q. Did you review -- conduct a comprehensive 24 review of the tests Bard or NMT actually did perform 25 before introducing this product to the market?</p>
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<p>1 see, again, how you could do that. You can calculate 2 that certainly, and I think that is what Professor 3 Begley did, but to measure -- actually measure that 4 would be a very difficult proposition. 5 Q. What is fretting fatigue? 6 A. When any two surfaces come into contact, even 7 small amounts of contact, they tend to disrupt the 8 surface. And that produces a local roughening of the 9 surface which can lead to the formation of fatigue 10 cracks. 11 So whenever you have two surfaces that are 12 articulating, a wire over the corner, or two wires 13 together, or something sliding over, or two plates that 14 are joined together, you can get this sort of rubbing, 15 which, again, it can trap moisture, but mainly it is 16 associated with the disruption of the surface. And 17 that can generate the presence of a crack, which then 18 grows under fatigue loading. 19 Q. Did you see any evidence of fretting fatigue 20 on these filters? 21 A. Yeah, the filters broke. I mean, the fact is 22 that there is such a rough surface, you couldn't see 23 much anyway. But certainly where you've got wires in 24 contact or similar together, that's where some of these 25 cracks began. So clearly fretting was involved.</p>	<p>1 A. The ones that I had been sent, yes. I looked 2 at the tests that were done for the 510K application. 3 I have found very little evidence of a stress analysis 4 on the other hand. I found very little evidence of a 5 proper characterization of the material that was used. 6 And -- but I have seen evidence of the series of 7 experiments or tests they did on these devices prior to 8 the submission to the FDA, which, by the way, I find to 9 be woefully inadequate. 10 Q. The only tests you saw were the ones provided 11 to you by Mr. Davis and Mr. Hartley, correct? 12 A. Indeed. Those were in response to 13 interrogatories, I presume, right? 14 Q. Were you given copies of the corrosion and 15 fatigue testing for the filter? 16 A. The ones that were submitted to the FDA, yes. 17 Q. You have, during the course of this day, made 18 a number of comments critical of the manufacturing 19 process for the filters. And you have also made a 20 number of comments critical of the surface quality and 21 other aspects of the materials utilized in the filter. 22 What specifically do you have as a criticism for the 23 design of the filter? 24 A. All these issues are interrelated. Remember, 25 I am looking at this from the failure. I am looking at</p>

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<p>1 it from something that is broken, and I am trying to 2 trace back and find out what caused that failure. So I 3 pointed out issues that I believe were contributing to 4 these -- these failures that I am looking at. 5 And certainly any design that has unbanded 6 corners or chamfers is somewhat suspect, in my opinion, 7 because it gives you an uncertainty in the stresses. 8 Any design where I don't see evidence of a 9 comprehensive stress analysis that reflects what is 10 interpreted to be the likely loading modes, I find to 11 be -- that's part of design. I haven't seen any 12 evidence of that. 13 And so those are the issues, and any design 14 which -- where you have got these rather severe defects 15 or imperfections in the surface, I mean, all of those 16 things appear to contribute to these failures. So that 17 is the basis of my criticisms, simply just coming out 18 of the facts that these seemed to cause the failures. 19 MR. NORTH: Okay. We are going to have to 20 change the tape right now. 21 THE VIDEOGRAPHER: This concludes Video No. 2 22 of the deposition of Robert Ritchie. Going off the 23 record. The time on the monitor is 2:19 p.m. 24 (Off the record from 2:19 p.m. 25 to 2:30 p.m.)</p>	<p>1 But I see very little evidence of an 2 appropriate analysis of the stresses, which I think is 3 one of the most important things in any design. And 4 the fact that how it performed in service is evidence 5 of the fact that there was not an appropriate analysis 6 of the stresses. So that aspect of the design is 7 severely lacking, in my opinion. 8 Q. Again, and that goes as I understand what you 9 just said to design processes that you believe were 10 flawed. I am asking from a design standpoint, a 11 configuration standpoint. Can you point to anything 12 specifically, other than the chamfer, that you believe 13 was inappropriate about the design? 14 A. I will reiterate, the stresses were too high 15 on the device. That is the design. I mean, that 16 speaks to many different features, you know, the way 17 that the thing operates, the thickness of the 18 components, the way it was manufactured -- there is a 19 multitude of issues there. 20 Whatever they were, the stresses were simply 21 too high in this device and that was associated with -- 22 is a multifaceted problem. It is associated with the 23 various different modes in which the device acted in 24 the body. It's associated with the condition of the 25 device, and it's associated with the geometry of the</p>
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<p>1 THE VIDEOGRAPHER: Here begins Video No. 3 of 2 the deposition of Robert Ritchie, Ph.D. Coming back on 3 the record. The time on the monitor is 2:30 p.m. 4 Please begin. 5 BY MR. NORTH 6 Q. Dr. Ritchie, we were talking about design 7 issues before we took a break to have the tape changed, 8 and I understand your position that, in your view, 9 there are design problems with this filter because it 10 did not perform in -- as it should have, in your view. 11 But you pointed to one specific aspect of the design 12 that you thought was improper, and that was the 13 chamfer. Did you point to any other specific aspects 14 of the design or configuration of the filter itself 15 that you believe is improper other than -- and I 16 understand the general notion that it should not be 17 failing. 18 A. Well, you know, in a design, one of the most 19 important aspects of a design is an appropriate 20 analysis of the stresses, because that, in essence, is 21 the reason why it could fail as a design. So to me, a 22 design of any component sets the values of stresses 23 amongst other things. This filter was apparently very 24 effective in catching -- doing what it was supposed to 25 do in catching clots.</p>	<p>1 device. 2 Q. Did you attempt to design an alternative 3 design for this product? 4 A. No, of course not. Why would I do that? 5 Q. Have you attempted to design or outline what 6 tests specifically should have been done to this 7 product before it was released to the market? 8 A. I have my opinions on that. I haven't 9 actually written them down, haven't been asked to put 10 them on paper, but certainly I have my opinions about 11 them. 12 Q. What are your opinions on that? 13 A. These opinions are based on, you know, my 14 general knowledge of how material -- how devices or 15 components in general fail and so forth. But I think 16 before any device that goes on the market, that 17 certainly we put in someone's body, most of the effort 18 should be put on an appropriate stress analysis that 19 tries to reflect the possible modes in which this 20 device can operate. 21 Secondly, I think that there should be a study 22 of the properties of the material. Now, I am basing 23 these comments, by the way, also on my experience with 24 other medical devices for other companies. And 25 thirdly, I think there should be an appropriate number</p>



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<p>1 of tests under conditions that reflect worst-case 2 conditions of the device itself. 3 Now, from what I have seen, which is the 4 papers that have been sent to me, I see very little 5 evidence of the comprehensive stress analysis on its 6 part, certainly very little reflection of the various 7 modes in which it can operate in vivo. Secondly, 8 the -- I don't see much evidence of the properties in 9 the material even being assessed. 10 And thirdly, the corrosion and fatigue testing 11 that was submitted to the FDA in 2001 and 2002 as part 12 of the 510K submission -- I don't know what other word 13 to use -- were pathetic. 14 Q. And how do you believe it was pathetic? 15 A. They tested 16 filters. They tested them for 16 36 million cycles, which, by my understanding, since 17 pulmonary cycles are typically assessed at 15 to 20 18 beats per minute, that is about three years' worth of 19 testing. They claim 10, but it is 3 to 4 in my 20 terminology. And they used a model where they 21 deflected the end -- they put it in a tube, and they 22 deflected the tube by a millimeter. Now I don't know 23 where they got that millimeter from, but clearly both 24 in terms of the number and the severity and the 25 duration of those tests, they -- and they were</p>	<p>1 which I think lasted -- it is a little unclear what 2 they did with respect to that. But in terms of 3 corrosion and fatigue, the study that was the most 4 definitive that I saw was the one that was submitted to 5 the FDA, and that was 36 million. 6 Q. So you didn't see any studies that had more 7 than 36 million cycles? 8 A. They may well have done them, but I didn't see 9 them defined very well. They didn't make any impact on 10 me, and certainly when I read it in the papers, I don't 11 think they were done in corrosion and fatigue of the 12 actual device. 13 Q. What sort of stress analysis testing did Bard 14 perform, that you saw? 15 A. I didn't see any. Your expert talks about a 16 computer study or something, and I have seen no 17 evidence of that. 18 Q. But again, with regard to Bard documents, your 19 review was limited to those documents that were 20 furnished to you by Mr. Davis and Mr. Hartley, correct? 21 A. Absolutely. 22 Q. I believe we have established this. You have 23 made no attempt to quantify the physiological loads, 24 and you would defer to Dr. McMeeking on that? 25 A. No. I mean, certainly I have not -- I mean, I</p>
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<p>1 inadequate. And as I understand it, they didn't appear 2 to look at these things afterwards other than just a 3 mere visual examination. 4 I believe the FDA, when I read from the notes 5 in the Kay Fullo deposition, requested that these 6 tested filters be looked at in the scanning electron 7 microscope. And as far as I understand, they never 8 were by Bard. So perhaps if they had looked at them, 9 they'd have seen the gouges. Perhaps they would have 10 seen evidence of cracks. 11 But when I have done IDEs and PMAs for other 12 device manufacturers, they involve huge arrays of 13 testing the material itself. A lot of effort is put 14 into stress analysis because that is one of the 15 critical issues, and there is generally a fair amount 16 of effort now put into testing the individual device 17 itself under, hopefully, you know, worst-case 18 conditions. And there is just no evidence of that 19 here. 20 Q. Was 36 million cycles the maximum the company 21 performed with regard to corrosion and fatigue testing? 22 A. For that 510K submission, yes. 23 Q. I am not talking about just limited to the 24 510K submission. 25 A. I don't know. I think they did other tests</p>	<p>1 don't any think either McMeeking or myself could easily 2 define the physiological loads. I mean, that is an 3 issue that certainly I wouldn't be able to do. So what 4 McMeeking, I think, did was to assume certain pressures 5 inside the artery and probably -- hopefully I am sure 6 worst-case pressures and based his analysis on that, 7 but I wouldn't have made any attempt to measure those. 8 Q. Outside of the context of this litigation, 9 have you ever conducted a stress analysis for a device 10 to determine or attempt to quantify physiological 11 loading? 12 A. Physiological loading is generally not 13 quantified with a stress analysis. It is generally 14 done by knowledge of the medical conditions. And so, 15 for example, for a heart valve, your blood pressure 16 maybe is 120-milligrams of mercury, so generally 17 speaking, the physiological loading would assume to be 18 something greater than that as a safety factor, 19 typically 150 or 200 or something like that. 20 Of late, now, people have started to do open 21 MRI, magnetic resonance measurements, to try to get 22 direct readings of the physiological loads. But that 23 is very, very recent sort of -- something I wouldn't 24 do. So generally, you assume a given pressure 25 associated with a part of the anatomy, which I think is</p>

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<p>1 fairly well understood by the medical community.</p> <p>2 Q. You, yourself personally, have you ever</p> <p>3 conducted any sort of analysis to determine the</p> <p>4 physiological loading forces for a particular device?</p> <p>5 A. Well, again, I reiterate, when I did the</p> <p>6 analysis on the heart valves, I assumed a certain value</p> <p>7 of -- I took a certain value of the blood pressure to</p> <p>8 base -- to do that analysis. So that is basically what</p> <p>9 I have done in that regard.</p> <p>10 Q. Have you seen any medical or other literature</p> <p>11 that attempts to quantify the physiological loads</p> <p>12 within the inferior vena cava?</p> <p>13 A. Yes, I've seen -- I mean, some of the</p> <p>14 documents I was given, I was seeing numbers -- a couple</p> <p>15 of people talked about, numbers like 15 milligrams of</p> <p>16 mercury. When you are sitting, it is about two to five</p> <p>17 milligrams of mercury, but for a worst-case you could</p> <p>18 assume some elevation of that. That is the extent of</p> <p>19 what I have seen, yes. Again, it is the pressure that</p> <p>20 is typically chosen.</p> <p>21 Q. Were those in medical articles that you saw,</p> <p>22 or were those in Bard internal documents, or do you</p> <p>23 recall?</p> <p>24 A. I don't recall. I think one -- I think I read</p> <p>25 one in one of these articles. I can't remember</p>	<p>1 A. So a designation of the Class-2 device I think</p> <p>2 was -- I mean, if you considered it to be a Class-2</p> <p>3 device, then it would have complied, but I think that</p> <p>4 decision was wrong on all counts.</p> <p>5 Q. Well, you are not sitting here disagreeing</p> <p>6 with the fact that the FDA classified this as a Class-2</p> <p>7 device at the time, correct?</p> <p>8 A. I am disagreeing with that.</p> <p>9 Q. You think the FDA did not classify it as 2 at</p> <p>10 that point?</p> <p>11 A. It was not a Class-2 device.</p> <p>12 Q. How was it characterized under the FDA</p> <p>13 regulations -- not what you say it should be -- how was</p> <p>14 it under the FDA regulations?</p> <p>15 A. It was classified as a Class-2 device because</p> <p>16 they said there was a similar device on the market, and</p> <p>17 that was the basis for the 510. That was a highly</p> <p>18 questionable and incorrect decision by all concerned.</p> <p>19 The device was different than the previous</p> <p>20 device, and therefore the stress analysis was totally</p> <p>21 different, and since the stress analysis is the most</p> <p>22 important aspect of the design, that decision -- I</p> <p>23 don't know if it was Bard or FDA or both -- in my</p> <p>24 opinion, it was a flawed decision. It is incorrect.</p> <p>25 Q. Okay. You have seen the 510K, correct?</p>
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<p>1 exactly. Certainly it was some comment of that in the</p> <p>2 depositions, and I think -- I think there was some</p> <p>3 assumption in one of the conditions for the Bard</p> <p>4 articles as well, so I think in possibly all three</p> <p>5 cases.</p> <p>6 Q. Now, you were furnished with some exemplar</p> <p>7 devices, correct?</p> <p>8 A. Yes, indeed.</p> <p>9 Q. Both the recovery filter and the G2?</p> <p>10 A. Yes, indeed.</p> <p>11 Q. And you did not conduct any fatigue tests on</p> <p>12 those exemplars, did you?</p> <p>13 A. No.</p> <p>14 Q. You did not conduct any kind of stress</p> <p>15 analysis with regard to them, did you?</p> <p>16 A. No. My purpose was to look at the surface and</p> <p>17 to look at the chamfer.</p> <p>18 Q. As you sit here today, do you know one way or</p> <p>19 the other whether Bard's testing for the recovery</p> <p>20 filter that it submitted to the FDA complied with the</p> <p>21 FDA's guidance regarding inferior vena cava filters?</p> <p>22 A. Well, that is an interesting question,</p> <p>23 actually. I don't think it should have gone through a</p> <p>24 510K.</p> <p>25 Q. That wasn't my question.</p>	<p>1 A. Uh-huh.</p> <p>2 Q. I'm sorry. You can't answer that way. "Yes"</p> <p>3 or "no"?</p> <p>4 A. Yes, yes, yes.</p> <p>5 Q. And you saw -- did you see correspondence from</p> <p>6 the FDA to Bard asking follow-up questions regarding</p> <p>7 the 510K?</p> <p>8 A. Yes.</p> <p>9 Q. And you did you see responses from Bard back</p> <p>10 to the FDA answering those?</p> <p>11 A. They sent answers back. In the case of</p> <p>12 fatigue and corrosion, they didn't answer the question,</p> <p>13 but they certainly sent responses back.</p> <p>14 Q. And the FDA cleared this device for --</p> <p>15 A. Yes.</p> <p>16 Q. -- commercial sale, correct?</p> <p>17 A. Yes. Yes, they did.</p> <p>18 Q. So if I understand your testimony, you are</p> <p>19 saying that Bard shouldn't have submitted it as a 510K,</p> <p>20 and the FDA shouldn't have cleared it as a 510K?</p> <p>21 A. It was a special 510K, and I think that -- in</p> <p>22 my opinion, that was an incorrect decision because</p> <p>23 there wasn't a similar device to compare it with -- to</p> <p>24 compare it to. The stress analysis was totally</p> <p>25 different. And I think the FDA actually made the wrong</p>

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<p>1 decision here, personally. It is not the first time 2 they have done that, by the way. 3 Q. So as you are sitting here today, it is your 4 understanding that this was submitted and cleared under 5 a special 510K? 6 A. Uh-huh. 7 Q. "Yes" or "no"? 8 A. Yes. That is my understanding. 9 Q. Have you ever prepared a 510K submission? 10 A. I have been part of submissions for IDEs and 11 PMAs. I have never been part of a 510K submission 12 before. 13 Q. Have you ever worked for the FDA? 14 A. No, not worked for the FDA. I have had a lot 15 of dealings with them over the last 20 years -- 30 16 years, in fact. 17 Q. Have you attempted to define specifically what 18 sort of stress analysis test should have been conducted 19 on these filters? 20 A. They should have calculated the stresses. 21 Presumably the best way to do it would be a numerical 22 analysis, and they should have done it under worst-case 23 conditions, and they should have considered the many 24 potential loading modes that they could experience. 25 And to my understanding they didn't do that.</p>	<p>1 the chamfer, because if the chamfer is unset, you can't 2 calculate the stresses to any accuracy -- the local 3 stresses. 4 Q. It sounds to me like you are agreeing with the 5 statement. I quote, "It is impossible to accurately 6 quantify the stresses in the filter where the wires 7 emanate from the surrounding sheath or cap." 8 A. If the chamfer is unset, yes. It is hardly an 9 excuse for not doing it, though. 10 Q. Do you know whether the diameter of the 11 inferior vena cava fluctuates? 12 A. Of course it does. 13 Q. Do you know the range in which it fluctuates? 14 A. Not exactly, no. 15 Q. Your report states at one point, "There is 16 evidence in published reports of Bard IVC filter 17 failures from computed tomography imaging in patients 18 that perforation of the device arms, and to a lesser 19 extent, the legs, occurs through the wall of the vena 20 cava vein." Do you recall that? 21 A. Yes. 22 Q. What was the basis of the statement? 23 A. Those images -- certainly in the Hull and 24 Robertson article, there is images of the -- tomography 25 images of the filters as it sits in the body. And</p>
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<p>1 Q. Would you agree with this statement: "It is 2 impossible to accurately quantify the stresses in the 3 implanted device where the wires emanate from the 4 surrounding sheath or cap." 5 A. Yeah, because they didn't fix the chamfer. 6 That was their mistake. 7 Q. I am not asking whether they fixed it or not. 8 I am asking, would you agree that it is impossible to 9 accurately quantify the stresses in the implanted 10 device where the wires emanate from the surrounding 11 sheath or cap? 12 A. Which implanted device? 13 Q. The filter. 14 A. If the chamfer had a fixed -- that was a fixed 15 value of the chamfer, it might be possible, but since 16 that is an unknown quantity, the stress concentration 17 from there can vary all over the map. So it is -- that 18 is a huge design fault to have a corner that -- so it 19 is very difficult to calculate the stress level under 20 these conditions because you don't know what the nature 21 of the design is there. 22 Q. My question is, would you agree with that 23 statement or not agree? 24 A. It is too imprecise a statement. Are you 25 referring to what device, what cap, under what value of</p>	<p>1 there is evidence that the -- these arms can perforate 2 the vena cava, and there is other reports of that in 3 other -- certainly the images that I remember most of 4 all would be tomography images in the Hull and 5 Robertson report. 6 Q. You haven't looked at any patients' medical 7 records that would demonstrate that, have you? 8 A. No. 9 Q. And you don't know how the perforation of the 10 Bard filters compares with the perforation rate of 11 competitive filters, do you? 12 A. No. I don't. 13 Q. Did you review the radial pull test performed 14 by Bard? 15 A. I looked at it, yes. 16 Q. As you sit here today, are you able to say 17 whether in the case of any of these particular 18 plaintiffs that you have been designated as an expert 19 for, the filter actually perforated the inferior vena 20 cava before fracturing? 21 A. I don't have exact knowledge of whether it did 22 or didn't. Just let me reiterate. I am looking at the 23 failures and trying to understand how these things 24 arose. And there is various features here that can 25 lead to these failures, and the fact that the -- that</p>

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<p>1 these cracks initiate on opposite sides of the wires 2 indicates a change in the stress states. 3 And there is evidence in the literature and in 4 the documents that I have read that these arms could 5 adhere to the sides of the vessel and also penetrate 6 them. And so that is clearly a mechanism by which the 7 stresses could increase quite dramatically, and I think 8 Bard recognized this, because they changed the nature 9 of the arms on the G2. So I don't think I am alone 10 there. But that is the basis of my decision here. 11 Q. Do you recall what fatigue or endurance limit 12 Bard utilized in its tests regarding Nitinol wire? 13 A. You know, I never saw the data that actually 14 specified that. But I -- there were numbers quoted, 15 and I think it may have come from the manufacturer. 16 And I seem to remember something like 40 to 50 KSI, or 17 150 to 200 mega-pascals. I think that is the number 18 that I saw. 19 But I would have liked to see some actual -- 20 what is called stress life curves or strain life 21 curves, like you see in that Patel report, for example, 22 which would have characterized the fatigue resistance 23 of this particular wire used in these devices. But I 24 didn't see any evidence of that in the papers I was 25 sent. I think there was a specification from the</p>	<p>1 A. No. I have them all here. I don't have a 2 listing. I mean, apart from the depositions which I 3 have given a list of, I have every document in my 4 suitcase here. And I think they are the ones that -- 5 at least part of the ones that you provided to 6 Mr. Hartley and Mr. Davis. 7 Q. Can you find for me what fatigue reports you 8 were provided? 9 A. The only ones I have are the ones that I 10 remember from the IDE application. And that is the Kay 11 Fullo deposition, which I don't actually have with me, 12 but it is in the back of that. It may appear 13 somewhere. 14 Q. Okay. That is enough of that -- am I correct 15 that the only fatigue test you saw and you reviewed are 16 those that were attached as exhibits to Kay Fullo's 17 deposition? 18 A. No, that is not right. But they were there. 19 They were definitely there. There is a document here 20 that talks about how they did the various different 21 tests involved, design review report. 22 Q. Okay. So you read a design review report. 23 Did you actually read any fatigue test? 24 A. I read the documents that were submitted to 25 the FDA as part of the 510, and I -- the place I found</p>
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<p>1 manufacturer of the material, which I think it was 100 2 to 150 mega-pascals. 3 Q. Do you think that is an appropriate number to 4 utilize? 5 A. It is difficult to -- it is a reasonable 6 number. You know, the fatigue limits of Nitinol are 7 generally specified in terms of strain rather than 8 stress. It is an appropriate number. It is a little 9 difficult to say, but that seems reasonable. 10 Q. Would you consider that a conservative 11 estimate? 12 A. I don't know. I didn't -- sorry, I am wrong. 13 Strike that. The numbers are 400 to 500 MPA. 14 Q. 400 to 500 what? 15 A. Mega-pascals. Okay, if you want in English 16 units, it is 60 to 75 KSI, which is a thousand pounds 17 per square inch. So is it a reasonable number? Yeah, 18 I think the numbers for Nitinol depend very much on how 19 it is heat-treated and its composition. That's why I 20 think it is important that you need to specify or do a 21 good characterization on this material. So 4- or 500 22 is in the range. But, as I said, I think that came out 23 of the specifications from the material manufacturer. 24 Q. Do you have a listing with you of all of the 25 documents you were provided?</p>	<p>1 those was in the Kay Fullo deposition. 2 Q. Other than what have been attached to the Kay 3 Fullo deposition, did you review any actual fatigue 4 reports from Bard? 5 A. There is a description of what they did here 6 and how they did the tests. 7 Q. I am talking about actual test reports. 8 A. Test reports, describing data? 9 Q. Right. 10 A. No. I didn't see any of those. 11 Q. Was there test reports describing data 12 attached to Kay Fullo's deposition or just summaries of 13 them? 14 A. Kay Fullo's report showed the -- what was 15 submitted to the FDA. So there is a summary -- there 16 is some more details in one of these documents here 17 about how they did the fatigue tests. Give me a second 18 here. Corrosion fatigue testing of Nitinol wire, there 19 is one here. 20 Q. Is that an actual test report? 21 A. Looks like it. 22 Q. What is the Bates-stamp on that? 23 A. 060100000274. 24 Q. What is the date of that? 25 A. 1997. There is another one here, a standard</p>

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<p>1 operating procedure. There is -- it doesn't really  2 contain much fatigue in there. There is a series of  3 reports in these which talk about the 16 tests that  4 were done and how they did them, and so forth. This  5 describes -- yeah, endurance test, corrosion fatigue,  6 NF filters, design verification.  7 Q. What is the date of that test?  8 A. August the 4th, 1999. And that is Bates stamp  9 2742. And that really just gives the details of these  10 16 filters that were subjected to 36 thousand --  11 million cycles at one millimeter deflection. And quite  12 frankly, the amount of information in this report was  13 not much more than what was in that summary of the Kay  14 Fullo deposition, but that was the important one.  15 Q. Okay. Let me ask you this: Were there actual  16 test reports in Kay Fullo's deposition or just a  17 summary?  18 THE DEPONENT: One moment, please.  19 THE VIDEOGRAPHER: Going off the record. The  20 time on the monitor is 3:01.  21 (Discussion off the record.)  22 THE VIDEOGRAPHER: Coming back on record. The  23 time on the monitor is 3:01 p.m. Please begin.  24 BY MR. NORTH  25 Q. As you sit here today, do you recall whether</p>	<p>1 Q. Exactly. You have seen what was sent to you,  2 correct?  3 A. Yes, obviously.  4 Q. Would you agree that prior to 2002, the cyclic  5 fatigue properties of Nitinol were not well understood?  6 A. No.  7 Q. You would not agree with that?  8 A. No.  9 Q. At what point do you believe that the cyclic  10 fatigue properties of Nitinol were well understood?  11 A. Too vague a question to answer. I mean, the  12 process of understanding is a continual thing. I mean,  13 the fatigue limits of Nitinol were first determined in  14 the '70s and '80s. And the alloy has changed somewhat  15 in its use, in its composition, and so it is a  16 continual evaluation. So the bottom line is, if you  17 are going to make something out of a particular alloy,  18 you ought to be able to characterize it whether it is  19 known or not.  20 It is incumbent upon you as a manufacturer of  21 the device to measure it, to calculate it. So there is  22 ample data in the literature prior to 2002 on the  23 fatigue of Nitinol. I have contributed to it myself.  24 Q. Would you agree that in 2004, data on fatigue  25 crack propagation in Nitinol was extremely limited?</p>
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<p>1 the exhibits or the materials you looked at that were  2 attached to Kay Fullo's deposition were actual test  3 reports?  4 A. No, they weren't. They were summaries.  5 Q. Simply summaries. Now when I am looking  6 through an index of the test reports that you were  7 provided by your -- by Mr. Hartley and Mr. Davis, it  8 looks like most of the test reports that you were given  9 were performed -- or all of them were performed between  10 1997 and 1999. Does that sound about right?  11 A. I didn't look very closely, but just on the  12 ones I looked at, that seems a reasonable assumption.  13 Q. And I also have some reports dated from 2000,  14 2001, that appear not to have been given to you.  15 A. On corrosion and fatigue?  16 Q. Yes.  17 A. Okay.  18 Q. Well, let me just ask you this. As you sit  19 here today, are you able to say one way or the other  20 whether you have seen all testing performed by Bard  21 regarding the recovery filter?  22 A. That is an impossible question to answer. I  23 have seen what was sent to me. I mean, there may have  24 been other tests. I couldn't possibly say anything,  25 talk to that.</p>	<p>1 A. Yes. That is a fracture mechanics approach  2 which is not necessarily used for small devices. So  3 these devices -- these wire devices and the tube  4 devices are not designed with fracture mechanics, so  5 you wouldn't necessarily use that data.  6 Q. But it is your testimony here today that as of  7 2002, the cyclic fatigue properties of Nitinol were  8 well understood?  9 A. Well, again, it is an impossible question to  10 answer. It's well understood. I mean, what do you  11 mean, the mechanisms? Do you mean -- you know, the  12 bottom line is we need to know what the data is.  13 Anybody can measure the data. So whatever alloy was  14 used, the data should have been measured. The people  15 should have measured -- so if a new alloy came  16 tomorrow, then we wouldn't have the data for it.  17 The process of understanding what fatigue is  18 in Nitinol, that is a different issue, the mechanistic  19 issues. They don't speak to a device. A device, you  20 just have to measure what is the fatigue limit, what is  21 the effect of notches.  22 That sort of information is basic information,  23 and if you were making a device in the '60s you would  24 simply have to measure that information or obtain it  25 some way. So it is not a question of being well</p>

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<p>1 understood or not; that is really a peripheral point.</p> <p>2 Mechanistically, we are learning all the time</p> <p>3 how Nitinol behaves. It's complicated material, but in</p> <p>4 terms of characterization of data, the procedures used</p> <p>5 to characterize the fatigue properties of Nitinol are</p> <p>6 the same today as they were in the last century.</p> <p>7 Q. Would you agree that the diameter of a Nitinol</p> <p>8 wire that is utilized would affect its fatigue</p> <p>9 properties?</p> <p>10 A. Inasmuch that it would affect the stresses on</p> <p>11 that wire, yes, it would. I mean, all other things</p> <p>12 being -- if the stress on the wire is the same, it</p> <p>13 wouldn't necessarily have that much of an effect.</p> <p>14 Q. Would you agree what the form of the Nitinol</p> <p>15 itself -- for example, whether it is in a thin-walled</p> <p>16 tube or wire would affect the fatigue properties?</p> <p>17 A. The -- in a normal material, it wouldn't make</p> <p>18 much effect. In Nitinol, it is important because there</p> <p>19 is slightly different textures, so it is important to</p> <p>20 characterize the same product form. So if you are</p> <p>21 making something out of a wire, it is important to test</p> <p>22 the wire. If you are making it out of a tube, it is</p> <p>23 important to test the tube.</p> <p>24 It is also important to test at the right</p> <p>25 temperature in relation to some of the temperatures of</p>	<p>1 to the stress analysis, one tends to try and take some</p> <p>2 degree of -- a factor of safety here. So, you know,</p> <p>3 typically what we do, you do your stress analysis on</p> <p>4 maybe the smallest valves or the smallest filters, the</p> <p>5 ones that you might perceive to have the higher</p> <p>6 stresses on.</p> <p>7 And you consider perhaps that if you -- if</p> <p>8 the -- you know the pressure in the pulmonary artery is</p> <p>9 considered to be 10 to 15, you might take a larger</p> <p>10 pressure just to give some degree of uncertainty. You</p> <p>11 know, in the aircraft industry, people say if the</p> <p>12 stresses ever get above 75 percent of the failure</p> <p>13 stresses, then you have, of course, the concerns. So</p> <p>14 you try to take a worst-case scenario.</p> <p>15 And in the testing, you would -- ideally you</p> <p>16 would need to see whether your devices or your wire,</p> <p>17 whatever, would be able to withstand not simply the</p> <p>18 life, but maybe a little bit more than the life that</p> <p>19 required, just to have that extra aspect of certainty.</p> <p>20 But the main thing is that you just have an appropriate</p> <p>21 stress analysis done and you have appropriate</p> <p>22 characterization of the material in which you make it</p> <p>23 out of in terms of the properties, and then you test</p> <p>24 the actual devices under conditions that reflect your</p> <p>25 perception of what they may see in vivo. So that's</p>
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<p>1 transformation in the material. And I have to say, on</p> <p>2 the -- when I looked at the data, it indicated quite a</p> <p>3 range for the transformation temperature, so that is</p> <p>4 something that I didn't really like either.</p> <p>5 Q. Would you agree that the properties of Nitinol</p> <p>6 are extremely sensitive to their precise chemical</p> <p>7 composition and processing treatment?</p> <p>8 A. Yes. Less so now than they used to be, but</p> <p>9 yes.</p> <p>10 MR. NORTH: Okay. Could we take a break? I</p> <p>11 think I am about finished.</p> <p>12 THE VIDEOGRAPHER: Going off the record. The</p> <p>13 time on the monitor is 3:10 p.m.</p> <p>14 (Off the record from 3:10 p.m.</p> <p>15 to 3:19 p.m.)</p> <p>16 THE VIDEOGRAPHER: Coming back on the record</p> <p>17 The time on the monitor is 3:19 p.m. Please begin.</p> <p>18 BY MR. NORTH</p> <p>19 Q. Dr. Ritchie, you made some references earlier</p> <p>20 to the notion of worst-case scenario testing.</p> <p>21 A. Uh-huh.</p> <p>22 Q. Would you define for me particularly what type</p> <p>23 of testing you believe should have been done to satisfy</p> <p>24 that requirement of worst-case scenario testing?</p> <p>25 A. It is a generic term, okay? So with respect</p>	<p>1 what I mean by worst case.</p> <p>2 Q. What type of equipment would you use to</p> <p>3 perform the kind of testing you just described?</p> <p>4 A. Well, it depends. The stress analysis, you'd</p> <p>5 need to use numerical analysis, or maybe you could do</p> <p>6 it analytically. We generally use -- element analysis</p> <p>7 is the best way to do that. The evaluation of the</p> <p>8 properties of the material that you make the device out</p> <p>9 of, that -- so you could use the manufacturer's data,</p> <p>10 but I don't think that is a good idea, because you want</p> <p>11 to have your own assessment.</p> <p>12 So you do fatigue tests and pieces of wire</p> <p>13 that you would cycle and -- in a physiological analogue</p> <p>14 environment over a range of stresses or strains to</p> <p>15 characterize the material. And then the actual device</p> <p>16 testing, you would essentially put it under a variety</p> <p>17 of tests, one where you put it in a sleeve like Bard</p> <p>18 did and then subject to it to certain pressures.</p> <p>19 But I think you would have to also simulate</p> <p>20 conditions that are not ideal, you know, perhaps if the</p> <p>21 thing doesn't seat properly or if the loading is</p> <p>22 somewhat asymmetric, and some of the things you can't</p> <p>23 test, so you may have to do computational theoretical</p> <p>24 estimates on what effect something would have or</p> <p>25 something else would have. And if something had a</p>

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<p>1 defect there and the stress was a little higher, I</p> <p>2 think you'd do those sort of tests.</p> <p>3 Q. As a part of your work in this case, you have</p> <p>4 not attempted to write an actual test protocol for the</p> <p>5 tests you are describing, have you?</p> <p>6 A. For the -- pertinent to this device?</p> <p>7 Q. Yes.</p> <p>8 A. No.</p> <p>9 Q. And you haven't tried to write any test</p> <p>10 procedure specific to this device, have you?</p> <p>11 A. No. I have told you, my philosophy is I was</p> <p>12 asked to examine why these things failed, and I looked</p> <p>13 and tried to understand why they have failed. And in</p> <p>14 the process of doing that, I have come to certain</p> <p>15 conclusions, and part of those conclusions are what I</p> <p>16 perceive to be some inadequacy in what was done when</p> <p>17 the device was designed, manufactured, and put into</p> <p>18 service.</p> <p>19 Q. With the understanding as always that under</p> <p>20 Rule 26 that requires supplementation if experts reach</p> <p>21 new and/or different opinions, and therefore you would</p> <p>22 have the obligation to give us prior notice of that, we</p> <p>23 will conclude the deposition at this time.</p> <p>24 MR. HARTLEY: Mind if I ask two questions,</p> <p>25 maybe?</p>	<p>1 implanted in the individuals, but I have every reason</p> <p>2 to believe that they would have failed in the same way,</p> <p>3 one of these modes, simply because they have the same</p> <p>4 filters and they are in a human being.</p> <p>5 So I would be extremely surprised if there was</p> <p>6 an alternative explanation for those failures. I</p> <p>7 haven't been able to look precisely, as no one has,</p> <p>8 because I haven't had the ability to look at the</p> <p>9 device. But if the arms or legs failed, it seems more</p> <p>10 than reasonable that it was associated with the</p> <p>11 mechanisms that I described.</p> <p>12 MR. HARTLEY: Can you say that with reasonable</p> <p>13 scientific probability?</p> <p>14 MR. NORTH: Objection to the form.</p> <p>15 THE DEPONENT: It is a difficult thing to say,</p> <p>16 but yes, I mean, because I haven't been able to look at</p> <p>17 them directly. But I have no reason to believe that</p> <p>18 they failed any different way.</p> <p>19 MR. HARTLEY: That is all I have.</p> <p>20 THE VIDEOGRAPHER: Off the record?</p> <p>21 MR. NORTH: Yes.</p> <p>22 THE VIDEOGRAPHER: This concludes Video No. 3</p> <p>23 of the deposition of Robert Ritchie, Ph.D. Going off</p> <p>24 the record. The time on the monitor is 3:26 p.m.</p> <p>25 (Whereupon the deposition was</p>
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<p>1 MR. NORTH: If you pay me.</p> <p>2 MR. HARTLEY: If I what?</p> <p>3 MR. NORTH: Pay me.</p> <p>4 MR. HARTLEY: You don't get to pay me.</p> <p>5 THE DEPONENT: The State of California should</p> <p>6 pay me.</p> <p>7 MR. HARTLEY: Dr. Ritchie, in your reports you</p> <p>8 have talked about the Muhaimin case, the Everett case,</p> <p>9 the Kolenda case and the Heidi Smith case, and the fact</p> <p>10 that you did not have filters that were removed from</p> <p>11 any of those four individuals to examine. In light of</p> <p>12 what you have reviewed for this matter, the exemplar</p> <p>13 filters, the materials from Bard, the filters that were</p> <p>14 explanted from the other individuals that you have, in</p> <p>15 fact, had an opportunity to review, do you have an</p> <p>16 opinion with reasonable scientific probability as to</p> <p>17 the likely cause of the fracture of the struts or the</p> <p>18 portions of the struts, the arms and legs, of Muhaimin,</p> <p>19 Everett, Kolenda and Smith's recovery filters?</p> <p>20 MR. NORTH: Objection to the form.</p> <p>21 THE DEPONENT: Can I answer the question?</p> <p>22 MR. NORTH: Yes.</p> <p>23 THE DEPONENT: As I understand it, there are</p> <p>24 arm and leg fractures in these devices. I haven't</p> <p>25 examined them because I can't. They are still</p>	<p>1 adjourned at 3:26 p.m.)</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: center;">SIGNATURE OF THE DEPONENT</p>

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DEPOSITION OF ROBERT O. RITCHIE, PH.D.

## CLARK REPORTING (510) 486-0700

Page 193	Page 195
<p>1                   DECLARATION</p> <p>2</p> <p>3           I, ROBERT O. RITCHIE, PH.D., do hereby declare</p> <p>4   under penalty of perjury that I have read the foregoing</p> <p>5   transcript of my deposition; that I have made such</p> <p>6   corrections as noted herein, in ink, initialed by me,</p> <p>7   or attached hereto; that my testimony as contained</p> <p>8   herein, as corrected, is true and correct.</p> <p>9           EXECUTED this ____ day of</p> <p>10   _____, 2011, at _____</p> <p>11   _____.</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18                   _____ ROBERT O. RITCHIE, PH.D.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1                   REPORTER'S CERTIFICATE</p> <p>2</p> <p>3</p> <p>4</p> <p>5           I, Joanna Broadwell, Certified Shorthand Reporter No.</p> <p>6   10959 in and for the State of California, hereby certify</p> <p>7   that the deponent,</p> <p>8           ROBERT O. RITCHIE, PH.D.,</p> <p>9</p> <p>10   was, by me, duly sworn to tell the truth, the whole</p> <p>11   truth, and nothing but the truth in the within-entitled</p> <p>12   cause; that the foregoing is a full, true and correct</p> <p>13   transcript of the proceedings had at the taking of said</p> <p>14   deposition, to the best of my ability.</p> <p>15</p> <p>16</p> <p>17</p> <p>18   Date: _____ Joanna Broadwell, CSR # 10959</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 194</p> <p>1           Clark Reporting and Videoconferencing</p> <p>2           2140 Shattuck Avenue, Suite 405</p> <p>3           Berkeley, California 94704</p> <p>4           (510) 486-0700</p> <p>5</p> <p>6           June 4, 2011</p> <p>7           ROBERT O. RITCHIE, PH.D.</p> <p>8           University of California</p> <p>9           Materials Science and Engineering</p> <p>10           Berkeley, CA 94720-1760</p> <p>11   Dear Deponent:</p> <p>12   Pursuant to the California Code of Civil Procedure, please</p> <p>13   be advised that the original transcript of your deposition</p> <p>14   taken on May 23, 2011 is ready for your review and</p> <p>15   corrections, if necessary. The original will be held in</p> <p>16   our office for a period of 35 days, at which time it will</p> <p>17   be forwarded to the noticing attorney.</p> <p>18</p> <p>19   If your attorney has ordered a copy, please review the</p> <p>20   transcript. Reading, correcting and signing of the</p> <p>21   deposition is an option and is not mandatory. If changes</p> <p>22   are necessary, please do so on the correction sheet</p> <p>23   provided.</p> <p>24</p> <p>25   If your attorney has not ordered a copy of the transcript,</p> <p>          you may call to make an appointment to review the original</p> <p>          in our offices.</p> <p>          Thank you,</p> <p>          Clark Reporting</p>	

49 (Pages 193 to 195)

DEPOSITION OF ROBERT O. RITCHIE, PH.D.

# **EXHIBIT F**



1 UNITED STATES DISTRICT COURT  
2 FOR THE  
3 DISTRICT OF ARIZONA  
4 \* \* \* \* \*  
In Re BARD IVC FILTERS PRODUCTS  
5 LIABILITY LITIGATION  
6 No. MD-15-02641-PHX-DGC  
\* \* \* \* \*  
7  
and  
8  
\* \* \* \* \*  
9 CAROL KRUSE )MDL No. 2641  
 )  
10 Plaintiff,) )  
 )  
11 vs. )  
 )  
12 C.R. BARD AND BARD )  
 PERIPHERAL VASCULAR, INC., )  
13 )  
 Defendant.)  
14 \* \* \* \* \*  
 DO NOT DISCLOSE - SUBJECT TO FURTHER  
15 CONFIDENTIALITY REVIEW  
16 VIDEOTAPED DEPOSITION OF: SHANON SMITH, M.D.  
17 DATE: April 4, 2017  
18 TIME: 2:00 p.m.  
19 PLACE: Mary Lanning Memorial Hospital, 15 North St.  
 Joseph Avenue, Hastings, Nebraska  
20  
21  
22  
23  
24  
25

Page 2	Page 4
<p>1 APPEARANCES</p> <p>2 APPEARING ON BEHALF OF PLAINTIFF:</p> <p>3 Thomas Wm. Arbon, Esquire</p> <p>4 LAW OFFICES OF BEN C. MARTIN, LLP</p> <p>5 3710 Rawlins Street, Suite 1230</p> <p>6 Dallas, Texas 75219</p> <p>7 (214)761-6614</p> <p>8 tarbon@bencmartin.com</p> <p>9 and</p> <p>10 Daniel MacDonald, Esquire</p> <p>11 BARON &amp; BUDD, P.C.</p> <p>12 3102 Oak Lawn Avenue, Suite 1100</p> <p>13 Dallas, Texas 75219</p> <p>14 (214)521-3605</p> <p>15 dmacdonald@baronbudd.com</p> <p>16 APPEARING ON BEHALF OF DEFENDANT BARD:</p> <p>17 Elizabeth C. Helm, Esquire</p> <p>18 NELSON MULLINS RILEY &amp; SCARBOROUGH LLP</p> <p>19 Atlantic Station</p> <p>20 201 17th Street NW, Suite 1700</p> <p>21 Atlanta, Georgia 30363</p> <p>22 (404)3226249</p> <p>23 kate.helm@nelsonmullins.com</p> <p>24 APPEARING ON BEHALF OF DEPONENT:</p> <p>25 Mark E. Novotny, Esquire</p> <p>LAMSON, DUGAN &amp; MURRAY LLP</p> <p>10306 Regency Parkway Drive</p> <p>Omaha, Nebraska 68114</p> <p>(402)397-7300</p> <p>mnovotny@ldmlaw.com</p> <p>ALSO PRESENT: Roger Speakman - Videographer</p>	<p>1 EXHIBITS: Marked</p> <p>2 2125 - Diagnostic imaging timeout 131</p> <p>3 2126 - E-mail 169</p> <p>4 2127 - Bates stamp No. KRUSEC_MLMH_MDR00057</p> <p>through 60 172</p>
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<p>1 INDEX</p> <p>2 WITNESS: Direct Cross Redirect Recross</p> <p>3 SHANON SMITH, M.D. 6 106 156 181</p> <p>4 184</p> <p>5 191</p> <p>6</p> <p>7 EXHIBITS: Marked</p> <p>8 2107 - Subpoena 7</p> <p>9 2108 - Curriculum Vitae 8</p> <p>10 2109 - IFU G2 filter system 29</p> <p>11 2110 - Bates stamp No. BPVE0100373887 42</p> <p>12 2111 - Bates stamp No. BPVE01-00622867 45</p> <p>13 2112 - Bates stamp No. BPVE010101982 50</p> <p>14 2113 - Bates stamp No. BPVE010752806 52</p> <p>15 2114 - Bates stamp No. BPV170100142912 57</p> <p>16 2115 - Hospital record 62</p> <p>17 2116 - Image RAD00011 64</p> <p>18 2117 - Fluoroscopic images 66</p> <p>19 2118 - Report dated April 7, 2011 72</p> <p>20 2119 - X-ray images 76</p> <p>21 2120 - Hospital chart record 81</p> <p>22 2121 - notes 83</p> <p>23 2122 - Hospital chart record 85</p> <p>24 2123 - Informed consent form 93</p> <p>25 2124 - Informed consent form 93</p>	<p>1 VIDEOGRAPHER: We are now on the</p> <p>2 record. My name is Roger Speakman, I am a</p> <p>3 videographer for Golkow Technologies. Today's</p> <p>4 date is April 4th, 2014 (sic) and the time is</p> <p>5 1412.</p> <p>6 This deposition is being held in Hastings,</p> <p>7 Nebraska, in the matter of Bard Filters Products</p> <p>8 Liability Litigation, Civil Action No.</p> <p>9 MD-15-02641-PHX-DGC with regard to Carol Kruse.</p> <p>10 In the United States District Court for the</p> <p>11 District of Arizona.</p> <p>12 The deponent is Shanon Smith, M.D.</p> <p>13 Counsels, will you please identify</p> <p>14 yourselves with firm affiliation and whom you</p> <p>15 represent.</p> <p>16 MR. ARBON: My name is Thomas</p> <p>17 Arbon. I'm with the law office of Ben C. Martin</p> <p>18 and we represent Carol Kruse.</p> <p>19 MR. MACDONALD: My name is Daniel</p> <p>20 MacDonald. I'm with the law firm of Baron and</p> <p>21 Budd and I represent Carol Kruse.</p> <p>22 MS. HELM: I'm Kate Helm with</p> <p>23 Nelson Mullins Riley &amp; Scarborough and I</p> <p>24 represent the defendants.</p> <p>25 MR. NOVOTNY: I am Mark Novotny</p>

<p style="text-align: right;">Page 6</p> <p>1 with Lamson Dugan and Murray in Nebraska and I'm</p> <p>2 her for Dr. Smith.</p> <p>3 VIDEOGRAPHER: Okay, the court</p> <p>4 reporter is Christine Salerno and will now swear</p> <p>5 in the witness.</p> <p>6</p> <p>7 SHANON SMITH, M.D.,</p> <p>8 Of lawful age, being first duly cautioned and</p> <p>9 solemnly sworn as hereinafter certified, was examined</p> <p>10 and testified as follows:</p> <p>11</p> <p>12 DIRECT EXAMINATION</p> <p>13 BY MR. ARBON:</p> <p>14 Q. Can I get you to state your full name, sir?</p> <p>15 A. Shanon Smith.</p> <p>16 Q. And Dr. Smith, how are you employed?</p> <p>17 A. I'm with a four-man radiology group that work at</p> <p>18 Mary Lanning.</p> <p>19 Q. How long have you been with that group?</p> <p>20 A. Since approximately 2009.</p> <p>21 Q. And Mary Lanning is what?</p> <p>22 A. The name of a hospital in Nebraska.</p> <p>23 Q. And where in Nebraska?</p> <p>24 A. Hastings, Nebraska.</p> <p>25 Q. All right. Do you perform -- do you have a</p>	<p style="text-align: right;">Page 8</p> <p>1 document?</p> <p>2 A. Let's see.</p> <p>3 (Discussion off the record.)</p> <p>4 A. Is in the --</p> <p>5 MR. NOVOTNY: Subpoena.</p> <p>6 A. Yeah, I believe it might be the subpoena.</p> <p>7 Q. (BY MR. ARBON) All right, Doctor, and that's</p> <p>8 what it is. And we'll talk in a minute, but the</p> <p>9 subpoena has an Exhibit A to it; do you see that?</p> <p>10 A. Okay.</p> <p>11 Q. Which was a request for some documents if you</p> <p>12 had them. And I just want to go through that real</p> <p>13 quick, see if there's some documents here that you</p> <p>14 have brought with you. Here's what we don't have,</p> <p>15 and the first is a copy of your current resume or CV?</p> <p>16 A. Correct.</p> <p>17 Q. Have you brought one with you?</p> <p>18 A. I think I saw somebody had --</p> <p>19 MR. NOVOTNY: We gave that to you</p> <p>20 previously.</p> <p>21 MR. ARBON: Okay, and that's what</p> <p>22 I'm just trying to make sure. If that's the</p> <p>23 case then let's go ahead.</p> <p>24 (Exhibit No. 2108, marked for identification.)</p> <p>25 Q. (BY MR. ARBON) I'm going to hand you now what</p>
<p style="text-align: right;">Page 7</p> <p>1 specific area of radiology that you practice?</p> <p>2 A. I practice in all areas.</p> <p>3 Q. Is your practice -- do you limit your practice</p> <p>4 to this hospital, Mary Lanning?</p> <p>5 A. No.</p> <p>6 Q. Okay. Do you have other hospitals that you</p> <p>7 practice for?</p> <p>8 A. Yes.</p> <p>9 Q. And what are they?</p> <p>10 A. They are several. Do you want me to list 'em?</p> <p>11 Q. Sure.</p> <p>12 A. Kearney hospital, Superior, Nebraska. Smith</p> <p>13 County, Kansas; Red Cloud, Nebraska; Osceola,</p> <p>14 Nebraska. I think those are the most common.</p> <p>15 Q. Okay. And you threw in a Kansas in there and</p> <p>16 which was that one?</p> <p>17 A. Oh, Kansas. Smith -- Smith County, Kansas.</p> <p>18 Q. Okay. How long has your radiology practice</p> <p>19 included these additional hospitals?</p> <p>20 A. In general, 2009.</p> <p>21 (Exhibit No. 2107, marked for identification.)</p> <p>22 Q. I think I'm going to get into that in a little</p> <p>23 more detail in a minute. But I'm asking you what</p> <p>24 I've marked -- take a look at the document I've</p> <p>25 marked as 2107 and ask you if you recognize that</p>	<p style="text-align: right;">Page 9</p> <p>1 we've marked as 2108 --</p> <p>2 A. Okay.</p> <p>3 Q. -- to your deposition, is that a copy of your --</p> <p>4 A. Correct.</p> <p>5 Q. Your current CV or resume?</p> <p>6 A. Yes.</p> <p>7 Q. All right. Is that an accurate copy of your</p> <p>8 resume?</p> <p>9 A. Yes.</p> <p>10 Q. And is it up to date?</p> <p>11 A. Yes.</p> <p>12 Q. All right. Do you have a patient medical file</p> <p>13 for Carol Kruse?</p> <p>14 A. The hospital has a medical file.</p> <p>15 Q. All right. But you don't maintain one</p> <p>16 separately in your own practice?</p> <p>17 A. Correct.</p> <p>18 Q. Did you have an opportunity to -- the next thing</p> <p>19 we asked for is medical imaging related to Carol</p> <p>20 Kruse, do you have any of that?</p> <p>21 A. The hospital has all that.</p> <p>22 Q. And let me just ask it this way: Have you</p> <p>23 brought any of that material with you?</p> <p>24 A. No.</p> <p>25 Q. Okay. Did you have any correspondence from any</p>

<p style="text-align: right;">Page 10</p> <p>1 physicians or medical facilities regarding Carol 2 Kruse? 3 A. No. 4 Q. And did you have any marketing materials or 5 other communications that you've ever received from 6 CR Bard or Bard Peripheral Vascular or anyone else 7 regarding their filters? 8 A. None other than what's on the internet for Bard, 9 and their G2 filter. 10 Q. So did you take a look at the internet for 11 materials related to the G2 or -- 12 A. They have a package insert on the internet. 13 Q. Any other documents, is that a document -- and I 14 know it's not necessarily a document in hand, it's 15 information on the internet. Are there any other 16 documents or information that you've reviewed to 17 prepare for the deposition today? 18 A. No. 19 Q. Doctor, have you ever given a deposition before? 20 A. Once. 21 Q. Uh-huh. And you are represented today by 22 Mr. Novotny; is that correct? 23 A. Correct. 24 Q. And we're taking this deposition here at Mary 25 Lanning Hospital in a conference room that you were</p>	<p style="text-align: right;">Page 12</p> <p>1 tell you no, all right? 2 A. (Witness nods.) 3 MR. NOVOTNY: That's a yes? 4 THE WITNESS: That's a yes. I 5 think I understand your question or statement. 6 Q. (BY MR. ARBON) All right. Let me try and 7 clarify. 8 If in order to answer my question what you're 9 going to have to say is oh, Mr. Novotny told me this, 10 I would rather you tell me the only way I know I can 11 answer that is based on what I've been told, we'll 12 move on -- we'll try to restate the question. 13 A. Okay. 14 Q. Next thing is, is if for some reason you would 15 like to take a break, let me know. 16 A. Okay. 17 Q. I may not be able to stop immediately if there's 18 a question pending or a line of questions, but I'll 19 get to the break as quick as I can. 20 A. Okay. 21 Q. Now Doctor, you understand that I represent 22 Carol Kruse in this matter? 23 A. That makes sense. 24 Q. Okay. And Ms. Kruse was one of your patients -- 25 A. Correct.</p>
<p style="text-align: right;">Page 11</p> <p>1 kind enough to help us arrange for, correct? 2 A. Correct. 3 Q. And so just a couple of things I will tell you 4 with regard to the deposition, and you're doing very 5 well. And the first thing is always, if you would 6 answer in words as opposed to a nod of the head or a 7 uh-huh or na-huh, 'cause the court reporter is trying 8 to make sure she gets a correct transcript and 9 sometimes it's difficult to interpret those, all 10 right? 11 A. Okay. 12 Q. The next thing I'm going to ask you, if for some 13 reason I ask you a question and you don't understand 14 it, if you would let me know and I'll try to rephrase 15 it so I can be sure you're answering the question I'm 16 asking, all right? 17 A. Okay. 18 Q. Tell you something else too that may come up. 19 If I ask a question and what you think I'm asking you 20 is to tell me about conversations you've had with 21 Mr. Novotny, your attorney, that's -- I promise you 22 that's not my intent. Communications that you've had 23 with your lawyer are not -- are privileged, I'm not 24 trying to ask that. So if you would just tell me, do 25 you mean what Mr. Novotny and I talked about, I will</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. -- is that correct? 2 We have met one time before, right? 3 A. Correct. 4 Q. And we spoke for a little bit before this -- 5 about the deposition and I asked you some questions 6 regarding your care of Ms. Kruse and your knowledge 7 of filters, right? 8 A. Correct. 9 Q. Other than that, we've had no communication 10 directly? 11 A. Other than the e-mail that you sent me saying 12 that you would like to meet. 13 Q. Okay. You understand this is a lawsuit in which 14 Ms. Kruse is alleging or brought claims against CR 15 Bard and Bard Peripheral Vascular with regard G2, the 16 G2 filter she had implanted? 17 A. Okay. 18 Q. What I'll also -- do you also understand that my 19 client has made no claims against you and has not 20 brought any, any lawsuit -- you're not a party to 21 this lawsuit, you just are a witness. 22 A. Okay. 23 Q. Can you tell me the address for your medical 24 practice. 25 A. 715 North St. Joseph, Hastings, Nebraska.</p>



<p style="text-align: right;">Page 14</p> <p>1 Q. Okay. And I think you said that they were, it's</p> <p>2 a radiology group comprised of four doctors?</p> <p>3 A. Correct.</p> <p>4 Q. Has that membership or that physician practice</p> <p>5 with your group remained constant since 2009?</p> <p>6 A. We had one member leave and then a new member</p> <p>7 replace a couple years ago.</p> <p>8 Q. Okay. Who are the members of the group now,</p> <p>9 there's yourself?</p> <p>10 A. Yes, Dr. Herold, H-E-R-O-L-D, Dr. Rodriguez, and</p> <p>11 Dr. Hart, H-A-R-T.</p> <p>12 Q. Okay. And who is the physician who left</p> <p>13 practice?</p> <p>14 A. Dr. Eric Rodriguez.</p> <p>15 Q. Okay. So we have two Dr. Rodriguez?</p> <p>16 A. Correct.</p> <p>17 Q. And who is the doctor that's still with the</p> <p>18 practice, the Dr. Rodriguez?</p> <p>19 A. His first name is Paul.</p> <p>20 Q. Okay. And who is the physician that joined the</p> <p>21 latest?</p> <p>22 A. Hart.</p> <p>23 Q. And when do you think he joined your firm, your</p> <p>24 group?</p> <p>25 A. Two to three years ago.</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Can you tell me the difference between a</p> <p>2 residency and a fellowship?</p> <p>3 A. A residency, you begin after your medical school</p> <p>4 and a fellowship, is additional training.</p> <p>5 Q. Is a residency more of a broad based medical</p> <p>6 education than a fellowship?</p> <p>7 MS. HELM: Object to the form.</p> <p>8 Q. (BY MR. ARBON) Let me try and rephrase it.</p> <p>9 A. Okay.</p> <p>10 Q. When you do residency, ever -- is it true that</p> <p>11 every doctor who's going to practice would generally</p> <p>12 have performed a residency?</p> <p>13 A. After you finish your residency, most doctors</p> <p>14 either go into practice or they specialize.</p> <p>15 Q. Okay. And residency is post the academic</p> <p>16 education of medical school, you go into residency</p> <p>17 for more of a clinical hands-on education in the</p> <p>18 practice of medicine; is that accurate?</p> <p>19 A. Yeah, you have more patient contact. I think</p> <p>20 that's accurate.</p> <p>21 Q. And is the focus of residency to expose doctors</p> <p>22 to several areas, specialties of medicine?</p> <p>23 A. Yes, that sounds reasonable.</p> <p>24 Q. And that's what I'm just getting to, is this</p> <p>25 is -- then when you go to a fellowship, then the</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. All right. And so it's 2007 (sic), so 2015,</p> <p>2 2014, somewhere in that range?</p> <p>3 A. That sounds reasonable.</p> <p>4 Q. Do you want to tell us where you received your</p> <p>5 medical degree?</p> <p>6 A. Medical College of Georgia.</p> <p>7 Q. And when did you receive that degree?</p> <p>8 A. Many years ago. Let's see, 2000 -- or 1992 is</p> <p>9 when I graduated.</p> <p>10 Q. All right. And where did you go to -- okay, so</p> <p>11 that's medical school at the Medical College of</p> <p>12 Georgia?</p> <p>13 A. Correct.</p> <p>14 Q. And did you do a residency?</p> <p>15 A. Yes.</p> <p>16 Q. And where did you do that?</p> <p>17 A. At Vanderbilt, in Nashville, Tennessee.</p> <p>18 Q. And how long was your residency?</p> <p>19 A. Three years.</p> <p>20 Q. And after your residency, did you do any other</p> <p>21 particular specialized training?</p> <p>22 A. A fellowship in occupational medicine and</p> <p>23 infectious disease from '95 to '98.</p> <p>24 Q. And where was that?</p> <p>25 A. University of Iowa.</p>	<p style="text-align: right;">Page 17</p> <p>1 physician after completing the residency, if I'm</p> <p>2 understanding the fellowship, as a physician you're</p> <p>3 going to seek out additional education in a more</p> <p>4 defined area of medicine?</p> <p>5 A. That sounds accurate.</p> <p>6 Q. And in your case, the first fellowship you</p> <p>7 obtained was an occupational medicine and infectious</p> <p>8 disease?</p> <p>9 A. Correct.</p> <p>10 Q. And can you give me a brief understanding of</p> <p>11 what that, what you learned through that fellowship?</p> <p>12 A. How to treat patients with on-the-job injuries</p> <p>13 and different unusual infections, in addition to</p> <p>14 general medicine.</p> <p>15 Q. And in looking at your resume, it referred to it</p> <p>16 as an internal medicine residency prior to your</p> <p>17 fellowship, so is your focus on internal medicine?</p> <p>18 A. Correct, primarily.</p> <p>19 Q. Give me a quick understanding of what internal</p> <p>20 medicine involves?</p> <p>21 A. Taking care of patients with many medical</p> <p>22 conditions.</p> <p>23 Q. And then, did you have any further specialized</p> <p>24 training in any areas of medicine in addition to your</p> <p>25 fellowship in occupational medicine and infectious</p>

<p style="text-align: right;">Page 18</p> <p>1 disease?</p> <p>2 A. Radiology and interventional radiology.</p> <p>3 Q. And when did you begin your fellowship in</p> <p>4 radiology?</p> <p>5 A. 2000 -- the residency began in 2004.</p> <p>6 Q. Okay. And where was that?</p> <p>7 A. Augusta, Georgia.</p> <p>8 Q. And in looking at your resume, it says</p> <p>9 diagnostic radiology. What is diagnostic radiology?</p> <p>10 A. It's the -- it's the study of radiology and all</p> <p>11 its components.</p> <p>12 Q. Does diagnostic radiology have more of a focus</p> <p>13 on, I would almost say diagnosis and recognition of</p> <p>14 conditions through imaging as opposed to treating?</p> <p>15 A. Not necessarily, can actually do both.</p> <p>16 Q. You completed that residency in 2008?</p> <p>17 A. Correct.</p> <p>18 Q. And then in 2008, you began a fellowship?</p> <p>19 A. Correct.</p> <p>20 Q. And that fellowship was in what area?</p> <p>21 A. Interventional radiology.</p> <p>22 Q. And what is interventional radiology?</p> <p>23 A. The study of radiology procedures that require</p> <p>24 more invasion to the body.</p> <p>25 Q. And by "invasion," what do you mean?</p>	<p style="text-align: right;">Page 20</p> <p>1 Before you finished your fellowship in 2009, did</p> <p>2 you have a practice that included interventional</p> <p>3 radiology?</p> <p>4 A. No, not a private practice.</p> <p>5 Q. Okay. And just to be a little, try and be a</p> <p>6 little clearer if I am. In doing interventional</p> <p>7 radiology procedures, more invasive procedures; first</p> <p>8 of all, is IVC filter placement considered an</p> <p>9 invasive procedure?</p> <p>10 A. I would, I would consider that.</p> <p>11 Q. Is that one of the procedures that you learned</p> <p>12 and added to your practice through your</p> <p>13 interventional radiology fellowship?</p> <p>14 MS. HELM: Object to the form.</p> <p>15 A. Actually, learned that in diagnostic radiology.</p> <p>16 You don't necessarily have to do an interventional</p> <p>17 fellowship, but you do learn that as well in the</p> <p>18 fellowship.</p> <p>19 Q. (BY MR. ARBON) When you were doing your</p> <p>20 diagnostic radiology residency, were you being</p> <p>21 instructed in how to perform IVC filter placement?</p> <p>22 A. Sometimes, if the patient arises.</p> <p>23 Q. And did you perform IVC filter placements during</p> <p>24 your residency in diagnostic radiology?</p> <p>25 A. I believe so.</p>
<p style="text-align: right;">Page 19</p> <p>1 A. Penetrating the skin.</p> <p>2 Q. And when did you complete your fellowship in</p> <p>3 interventional radiology?</p> <p>4 A. 2009.</p> <p>5 Q. And do you know when in 2009 that was?</p> <p>6 A. Most trans -- most people transition by July the</p> <p>7 1st.</p> <p>8 Q. And that fellowship, if I'm looking at it, is</p> <p>9 University of Nebraska at Omaha?</p> <p>10 A. Correct.</p> <p>11 Q. And how far is that facility from here in</p> <p>12 Hastings?</p> <p>13 A. Three hours by car. If you drive the</p> <p>14 appropriate speed.</p> <p>15 Q. And so is it fair to say you completed your</p> <p>16 fellowship in interventional radiology around July of</p> <p>17 2009?</p> <p>18 A. I think that would be accurate.</p> <p>19 Q. Before you completed your residency, were you</p> <p>20 practicing interventional radiology?</p> <p>21 A. Before I completed --</p> <p>22 MR. NOVOTNY: No, you said</p> <p>23 residency.</p> <p>24 Q. (BY MR. ARBON) I'm sorry, I'll withdraw the</p> <p>25 question.</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. Okay. And then did you perform additional</p> <p>2 filter placement procedures during your fellowship in</p> <p>3 interventional radiology?</p> <p>4 A. Yes.</p> <p>5 Q. And then once you completed your fellowship,</p> <p>6 what did -- what was your next move in terms of your</p> <p>7 professional career?</p> <p>8 A. Private practice to where I am currently.</p> <p>9 Q. Once you moved into private practice, did you</p> <p>10 include the placement of enter -- enter -- start</p> <p>11 over.</p> <p>12 Once you moved into private practice, did you</p> <p>13 include the placement of IVC filters as part of the</p> <p>14 services you could offer as a physician?</p> <p>15 A. Yes, they were included.</p> <p>16 Q. When you went into private practice, did your</p> <p>17 private practice include the different hospitals that</p> <p>18 we've discussed, Mary Lanning, Kearney hospital,</p> <p>19 Superior, Smith County, Red Cloud and Osceola, were</p> <p>20 all those hospitals in your -- part of your practice?</p> <p>21 A. Yeah. Yes.</p> <p>22 Q. How long have you had -- do you have staff</p> <p>23 privileges in all those facilities?</p> <p>24 A. Yes.</p> <p>25 Q. And how long have you had staff privileges at</p>

<p style="text-align: right;">Page 22</p> <p>1 each of those hospitals?</p> <p>2 A. Since 2009, I believe.</p> <p>3 Q. Okay. And would that have -- those staff</p> <p>4 privileges come when you finished your fellowship or</p> <p>5 before?</p> <p>6 A. After fellowship.</p> <p>7 Q. I'm sorry, are you board certified?</p> <p>8 A. I am board certified.</p> <p>9 Q. In what areas?</p> <p>10 A. Radiology, internal medicine, infectious</p> <p>11 disease, occupational medicine.</p> <p>12 Q. Is there a board certification for</p> <p>13 interventional radiology?</p> <p>14 A. Yes.</p> <p>15 Q. Do you hold that certification?</p> <p>16 A. Not yet.</p> <p>17 Q. Okay. Are you board eligible in that area?</p> <p>18 A. Yes.</p> <p>19 Q. I'm assuming you just haven't sat for the boards</p> <p>20 yet?</p> <p>21 A. It's a \$4,000 out of town rigorous, so not yet.</p> <p>22 Q. All right. Can you give me an idea and I'm just</p> <p>23 going to ask you: Is Hastings a small town?</p> <p>24 A. Some people may say so.</p> <p>25 Q. Okay. What do you say?</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. What is ARRS?</p> <p>2 A. American Roentgen Ray Society. Good luck on</p> <p>3 spelling that.</p> <p>4 Q. And what is that society?</p> <p>5 A. That's a radiology society.</p> <p>6 Q. Are you part of the society of interventional</p> <p>7 radiologists?</p> <p>8 A. I used to be.</p> <p>9 Q. Okay. And when were you a part of that society?</p> <p>10 A. I would guess between 2009 and until a couple</p> <p>11 years ago.</p> <p>12 Q. And 2017, so 2015-ish, '14, '15?</p> <p>13 A. That sounds reasonable.</p> <p>14 Q. And is there a reason that you're not part of</p> <p>15 that society anymore?</p> <p>16 A. I felt that the ARRS covered the same topics</p> <p>17 they did. And being a member of many societies is</p> <p>18 extremely expensive so I focused on ARRS.</p> <p>19 Q. Have you ever been or are you currently a</p> <p>20 reviewer for any medical journals?</p> <p>21 A. No.</p> <p>22 Q. Do you have a recollection of Carol Kruse as a</p> <p>23 patient?</p> <p>24 A. I remember the room and the procedure, but I</p> <p>25 don't recall her specifically, color of her hair or</p>
<p style="text-align: right;">Page 23</p> <p>1 A. I would call it a small town.</p> <p>2 Q. Okay. I mean, you've been trained in Georgia</p> <p>3 and --</p> <p>4 A. Uh-huh.</p> <p>5 Q. -- you've been trained in -- Vanderbilt, is that</p> <p>6 Memphis? Nashville?</p> <p>7 A. Tennessee, it's a larger town.</p> <p>8 Q. Which is?</p> <p>9 A. Nashville.</p> <p>10 Q. Okay.</p> <p>11 A. And Memphis.</p> <p>12 Q. Okay. And I just, I mean, as a physician who is</p> <p>13 board certified in radiology, internal medicine,</p> <p>14 occupational medicine, infectious disease in a</p> <p>15 smaller town or smaller hospital, I assume all of</p> <p>16 your training comes to bear; is that fair?</p> <p>17 MS. HELM: Object to the form.</p> <p>18 A. It's nice to have as much training as you can,</p> <p>19 that's for sure.</p> <p>20 Q. (BY MR. ARBON) Are you still called upon to</p> <p>21 provide opinions or assist patients in areas other</p> <p>22 than radiology?</p> <p>23 A. Yes.</p> <p>24 Q. Are you a member of any professional societies?</p> <p>25 A. ARRS.</p>	<p style="text-align: right;">Page 25</p> <p>1 things like that.</p> <p>2 Q. Okay. And you say room and her procedure and</p> <p>3 I'm just going to, as you know, you actually</p> <p>4 performed two procedures related to her --</p> <p>5 A. Yes, correct.</p> <p>6 Q. -- which procedure do you recall?</p> <p>7 A. The second one I recall the most.</p> <p>8 Q. Okay. Is there a reason why you recall that</p> <p>9 second procedure more?</p> <p>10 A. 'Cause we tried to retrieve a filter and did not</p> <p>11 retrieve a filter.</p> <p>12 Q. Do you remember what type of filter it was?</p> <p>13 A. I believe it's a G2 filter.</p> <p>14 Q. Do you recall if there was anybody else in</p> <p>15 that -- was it a cath lab or operating room?</p> <p>16 A. It's a interventional room, interventional</p> <p>17 suite.</p> <p>18 Q. Did you have anybody else present with you in</p> <p>19 the interventional suite, other than the patient?</p> <p>20 A. An x-ray tech.</p> <p>21 Q. Okay. Anyone else?</p> <p>22 A. That's the one I recall.</p> <p>23 Q. Okay. Was there a Bard representative present</p> <p>24 for that procedure?</p> <p>25 A. I don't recall.</p>

<p style="text-align: right;">Page 26</p> <p>1 Q. Okay.</p> <p>2 A. For the first, for the first -- for the first --</p> <p>3 the placement, I don't recall.</p> <p>4 Q. Okay. And that may be where we've gotten</p> <p>5 crossed I'm still talking about the retrieval</p> <p>6 procedure.</p> <p>7 A. Okay, sorry. For the retrieval, yes, there was</p> <p>8 a Bard representative, don't remember his name.</p> <p>9 Q. But it was a male?</p> <p>10 A. It was a man.</p> <p>11 Q. I've been told that there was a gentleman by the</p> <p>12 name of Brofy Puckett (sic) that was assigned to this</p> <p>13 territory at that time, do you know Mr. Puckett?</p> <p>14 A. No.</p> <p>15 Q. Do you know if that was -- so by saying that, do</p> <p>16 you know if that was or was not Mr. Puckett that was</p> <p>17 present?</p> <p>18 A. I don't know.</p> <p>19 Q. When there's a representative present during a</p> <p>20 procedure like that, would there be any documents</p> <p>21 generated to identify that they were -- by the</p> <p>22 hospital to identify that they were present?</p> <p>23 A. I don't -- I don't know what the hospital policy</p> <p>24 was at that time.</p> <p>25 Q. How is it you're so sure that he was present?</p>	<p style="text-align: right;">Page 28</p> <p>1 A. To discuss that, what my plan was was</p> <p>2 appropriate. And if it -- and if the plan didn't</p> <p>3 work, what would be alternate plans.</p> <p>4 Q. Did you look at the Bard representatives as some</p> <p>5 kind of a resource for information on the product?</p> <p>6 MS. HELM: Object to the form.</p> <p>7 A. I look for them as a resource for their clinical</p> <p>8 expertise.</p> <p>9 Q. (BY MR. ARBON) And in light of the objection,</p> <p>10 let me ask the question a different way.</p> <p>11 What did you look for or what did you hope to</p> <p>12 gain by having a Bard representative present during</p> <p>13 Ms. Kruse's explantation procedure?</p> <p>14 A. I would want, let's see, I -- how -- can you</p> <p>15 repeat the question?</p> <p>16 Q. I'm going to broaden it up first, because that</p> <p>17 may have hung you up.</p> <p>18 When you request to have a Bard representative</p> <p>19 present during any procedure, why are you making that</p> <p>20 request? What is your expectation with regard to the</p> <p>21 Bard representative's being -- being at the</p> <p>22 procedure?</p> <p>23 MS. HELM: Object to the form.</p> <p>24 A. I would request the representative be there in</p> <p>25 case I had any questions that need to be answered.</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Because I remember him being there.</p> <p>2 Q. How -- in your practice, how often would you</p> <p>3 have a product manufacturer representative available</p> <p>4 during a procedure?</p> <p>5 A. Most times they are available.</p> <p>6 Q. Is that usually something -- well, could you</p> <p>7 tell me how this particular rep came to be present</p> <p>8 during this -- Ms. Kruse's retrieval procedure?</p> <p>9 A. Because we would have asked him to be there.</p> <p>10 Q. Okay. So that would have been arranged through</p> <p>11 your office?</p> <p>12 Or through the hospital?</p> <p>13 A. Through the hospital.</p> <p>14 Q. And why would you have asked for him to be</p> <p>15 there?</p> <p>16 A. Because it's always nice to have help.</p> <p>17 Q. And how, what kind of help would the -- the Bard</p> <p>18 representative provide?</p> <p>19 A. Suggestions, if needed.</p> <p>20 Q. And I'm going to have to get kind of more detail</p> <p>21 on that, but --</p> <p>22 A. Sure.</p> <p>23 Q. By suggestions, what kind of suggestions might</p> <p>24 you expect or might you look to the Bard</p> <p>25 representative for?</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. (BY MR. ARBON) And when you say, "any questions</p> <p>2 that need to be answered," any questions about the</p> <p>3 entire procedure or things in general or what are you</p> <p>4 looking to the Bard rep for?</p> <p>5 MS. HELM: Object to the form.</p> <p>6 A. It could be any question that I pose, if he felt</p> <p>7 comfortable answering.</p> <p>8 Q. (BY MR. ARBON) Can you give me an example of</p> <p>9 some of the discussions you've had with the Bard reps</p> <p>10 that have been present during filter procedures that</p> <p>11 you've performed?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 A. I remember in this particular case when we were</p> <p>14 attempting to retrieve it, the suggestion was to do a</p> <p>15 loop technique, but we had decided not to do that and</p> <p>16 refer the patient to a tertiary care facility.</p> <p>17 That's our, that's why I remember a rep was in the</p> <p>18 room.</p> <p>19 Q. Okay.</p> <p>20 (Exhibit No. 2109, marked for identification.)</p> <p>21 Q. I hand you what I've marked as document Exhibit</p> <p>22 No. 1209.</p> <p>23 MS. HELM: 2109.</p> <p>24 MR. ARBON: Let me rephrase.</p> <p>25 Q. (BY MR. ARBON) Let me show you what I've handed</p>



<p style="text-align: right;">Page 30</p> <p>1 you as Exhibit No. 2109 and ask you if you recognize</p> <p>2 that document?</p> <p>3 A. I believe this is the same package insert that</p> <p>4 you see on the internet.</p> <p>5 Q. Okay. Does this appear to be the package insert</p> <p>6 that would have been available to you at the time</p> <p>7 Ms. Kruse's filter was explanted?</p> <p>8 A. Most of the time they're in the box.</p> <p>9 Q. What is an IFU?</p> <p>10 A. I don't know.</p> <p>11 Q. Instructions for use?</p> <p>12 A. Okay.</p> <p>13 Q. Okay. I'm sorry, this document -- let's just</p> <p>14 talk about the G2 filter system information for use</p> <p>15 document you have in front of you. I mean, had you</p> <p>16 seen that before you attempted to both -- well,</p> <p>17 implant the filter in Ms. Kruse?</p> <p>18 A. I don't, I don't know.</p> <p>19 Q. Okay. Did you see instructions for use when you</p> <p>20 were training to use the G2 device?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And so you're familiar with the</p> <p>23 instructions for use for that device?</p> <p>24 MS. HELM: Object to the form.</p> <p>25 A. I've been trained to place the device and I've</p>	<p style="text-align: right;">Page 32</p> <p>1 A. I could guess. Do you mean like --</p> <p>2 MR. ARBON: I'll withdraw the</p> <p>3 question.</p> <p>4 (Court reporter interrupted for clarification.)</p> <p>5 Q. (BY MR. ARBON) Where did you receive your</p> <p>6 training on the placement of IVC filters?</p> <p>7 A. It would have been in Georgia and Nebraska.</p> <p>8 Q. And specific to a Bard G2 filter, where did you</p> <p>9 receive training on the use of the Bard G2 filter?</p> <p>10 A. In Nebraska for sure. Unsure if Georgia carried</p> <p>11 that product at the time.</p> <p>12 Q. When you were going through your fellowship in</p> <p>13 interventional radiology at the University of</p> <p>14 Nebraska in Omaha, as part of your training, were</p> <p>15 Bard representatives ever present during your</p> <p>16 training on the use of the Bard products?</p> <p>17 MS. HELM: Object to the form.</p> <p>18 A. Sometimes representatives were there for</p> <p>19 multiple companies for different products that they</p> <p>20 had.</p> <p>21 Q. (BY MR. ARBON) Okay. And in this case, we're</p> <p>22 specifically dealing with the Bard G2, obviously,</p> <p>23 filter products. Do you recall when you were</p> <p>24 training -- in training in your fellowship at the</p> <p>25 University of Nebraska Omaha, did Bard have</p>
<p style="text-align: right;">Page 31</p> <p>1 read through this document before.</p> <p>2 Q. (BY MR. ARBON) Do you consider an instruction</p> <p>3 for use a document that is a benefit to you as a</p> <p>4 physician that's going to be using the product?</p> <p>5 A. Yes.</p> <p>6 Q. What do you use -- why do you consult or read an</p> <p>7 instruction for use document such as the G2 document</p> <p>8 you have in front of you?</p> <p>9 A. To try to do the steps that are recommended.</p> <p>10 Q. Where were you trained to place G2 filters?</p> <p>11 MS. HELM: Object to the form.</p> <p>12 A. That's, that's -- I'm not sure what that means?</p> <p>13 MS. HELM: You mean, like, in</p> <p>14 what --</p> <p>15 A. In a patient or --</p> <p>16 MS. HELM: Like in a state or --</p> <p>17 (Court reporter interrupted for clarification.)</p> <p>18 MS. HELM: Or an interior vena</p> <p>19 cava?</p> <p>20 MR. NOVOTNY: I knew what you</p> <p>21 meant.</p> <p>22 A. Honestly --</p> <p>23 MR. ARBON: I honestly didn't</p> <p>24 think we were going to head that, get confused</p> <p>25 that quickly.</p>	<p style="text-align: right;">Page 33</p> <p>1 representatives there available as a resource for the</p> <p>2 students that were learning to use the product?</p> <p>3 MS. HELM: Object to the form.</p> <p>4 A. I remember seeing a Bard representative at</p> <p>5 the -- at the University of Nebraska.</p> <p>6 Q. (BY MR. ARBON) And again, was that</p> <p>7 representative available, similar to as we discussed</p> <p>8 when you have procedures, to answer questions,</p> <p>9 provides suggestions to assist you in your</p> <p>10 understanding of the use of the products?</p> <p>11 MS. HELM: Object to the form.</p> <p>12 A. It could.</p> <p>13 Q. (BY MR. ARBON) Did you ever utilize them for</p> <p>14 that?</p> <p>15 A. Sometimes.</p> <p>16 Q. Did you view them, again, as kind of a resource</p> <p>17 for information on the Bard product?</p> <p>18 MS. HELM: Object to the form.</p> <p>19 A. Found their advice sometimes helpful.</p> <p>20 Q. (BY MR. ARBON) Did you have any expectations</p> <p>21 about the level of education and training that that</p> <p>22 representative would have with regard to the product?</p> <p>23 A. I assume they understood their product.</p> <p>24 Q. Would you expect -- was it your expectation the</p> <p>25 manufacturer would make sure that the Bard</p>

<p style="text-align: right;">Page 34</p> <p>1 representatives they made available to you were</p> <p>2 knowledgeable with regard to the capabilities of the</p> <p>3 Bard products?</p> <p>4 MS. HELM: Object to the form.</p> <p>5 A. I would assume as an employee they should be</p> <p>6 trained appropriately.</p> <p>7 Q. (BY MR. ARBON) Okay. And I'm getting to be --</p> <p>8 should be trained appropriate to discuss the</p> <p>9 capabilities of the product.</p> <p>10 MS. HELM: Object to the form.</p> <p>11 A. The product and -- correct, the product.</p> <p>12 Q. (BY MR. ARBON) Would you expect that Bard</p> <p>13 representative to be knowledgeable if there are any</p> <p>14 limitations with the product?</p> <p>15 MS. HELM: Object to the form.</p> <p>16 A. The rep should know the product well.</p> <p>17 Q. (BY MR. ARBON) Good. And so if the product --</p> <p>18 if within Bard there's knowledge that Bard has</p> <p>19 regarding their product which indicates there may be</p> <p>20 some limits or there may be issues related to</p> <p>21 complications caused by their product, would you</p> <p>22 anticipate that that Bard rep would convey them to</p> <p>23 you as the physician who is making decisions about</p> <p>24 using the product?</p> <p>25 MS. HELM: Object to the form.</p>	<p style="text-align: right;">Page 36</p> <p>1 looking at Page 1.</p> <p>2 MR. NOVOTNY: Here. (Indicating.)</p> <p>3 Q. Under indication for use.</p> <p>4 A. Okay, yes, I see that.</p> <p>5 Q. And you see it?</p> <p>6 A. Yes.</p> <p>7 Q. But let's just take indications for use in</p> <p>8 general.</p> <p>9 A. Okay.</p> <p>10 Q. Is that an area that you, as a physician who is</p> <p>11 going to be utilizing Bard products, would expect the</p> <p>12 Bard rep that you're working with to be knowledgeable</p> <p>13 about, the indications for use?</p> <p>14 MS. HELM: Object to the form.</p> <p>15 A. Yes.</p> <p>16 Q. (BY MR. ARBON) What is your understanding or</p> <p>17 expectation when a manufacturer such as Bard</p> <p>18 represents that a IVC filter is indicated for use for</p> <p>19 the prevention of recurrent pulmonary embolism by a</p> <p>20 permanent placement. What does that mean to you?</p> <p>21 MS. HELM: Object to the form.</p> <p>22 A. That the product can be used for that indication</p> <p>23 and the physician would be correct in putting it in</p> <p>24 for that reason.</p> <p>25 Q. (BY MR. ARBON) If Bard makes that representation</p>
<p style="text-align: right;">Page 35</p> <p>1 A. Yes, I would think the rep would tell us risk</p> <p>2 and benefits of the product.</p> <p>3 Q. (BY MR. ARBON) Is that one of the things that</p> <p>4 you would look to the Bard rep for?</p> <p>5 A. Yes.</p> <p>6 Q. So if a Bard rep tells you that a G2 -- well,</p> <p>7 let's just take the IFU for example.</p> <p>8 A. Okay.</p> <p>9 Q. If the Bard rep -- if the Bard and through its</p> <p>10 representatives -- and when I say reps, you</p> <p>11 understand I mean sales representatives?</p> <p>12 A. Correct.</p> <p>13 Q. I believe in Bard they're, territory managers is</p> <p>14 their title.</p> <p>15 A. Okay.</p> <p>16 Q. For example, if the Bard rep were to tell you,</p> <p>17 "The G2 filter system is indicated for use in the</p> <p>18 prevention of recurrent pulmonary embolism by a</p> <p>19 permanent placement in vena cava in the following</p> <p>20 situations," if a Bard rep makes that representation,</p> <p>21 you would expect that they would be knowledgeable</p> <p>22 about that representation; is that fair?</p> <p>23 MS. HELM: Object to the form.</p> <p>24 A. Are you reading from this list?</p> <p>25 Q. (BY MR. ARBON) yes, for example, I'm just</p>	<p style="text-align: right;">Page 37</p> <p>1 to you, what as a physician, do you believe would</p> <p>2 have gone into Bard's -- strike that. Let me try and</p> <p>3 rephrase.</p> <p>4 As a physician who is being asked to use this</p> <p>5 filter and place it in patient, if Bard makes</p> <p>6 representation that the filter is indicated for use</p> <p>7 in the prevention of recurrent pulmonary embolism by</p> <p>8 a permanent placement, would you anticipate that Bard</p> <p>9 has fully tested the product to determine whether</p> <p>10 it's safe for that purpose and for permanent</p> <p>11 placement?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 A. I would assume the company's checked safety and</p> <p>14 efficacy of the filter.</p> <p>15 Q. (BY MR. ARBON) Would you anticipate the company</p> <p>16 has verified the long-term safety of the product if</p> <p>17 they're recommending it for permanent use?</p> <p>18 MS. HELM: Object to the form.</p> <p>19 A. I would -- I would think that's part of the FDA</p> <p>20 process, is long-term assessment.</p> <p>21 Q. (BY MR. ARBON) And what's your understanding of</p> <p>22 how -- of the FDA process, do you have one?</p> <p>23 A. The FDA, when a product is approved, then</p> <p>24 there's a post follow-up of that follow-up -- of that</p> <p>25 product.</p>

<p style="text-align: right;">Page 38</p> <p>1 Q. Was it your belief or your understanding that</p> <p>2 the Bard G2 filter had gone through an FDA approval</p> <p>3 process?</p> <p>4 MS. HELM: Object to the form.</p> <p>5 A. The -- I assume that there was some process that</p> <p>6 it would be regulated before it went on the market.</p> <p>7 Q. (BY MR. ARBON) Did your Bard rep or anyone with</p> <p>8 Bard represent to you that it was an FDA approved</p> <p>9 device?</p> <p>10 A. I can't recall that they used those words.</p> <p>11 Q. Okay. Would it surprise you to learn that an</p> <p>12 FDA approval was not provided for the filter?</p> <p>13 MS. HELM: Object to the form.</p> <p>14 It...</p> <p>15 A. I wouldn't know that. I think you mentioned</p> <p>16 that earlier in our meetings earlier, but I wouldn't,</p> <p>17 I didn't...</p> <p>18 Q. (BY MR. ARBON) In fact, what the Bard G2 filter</p> <p>19 did is went through the process called a 510K</p> <p>20 proceeding, which does not involve approval by the</p> <p>21 FDA, merely clearance based on a representation that</p> <p>22 it is as safe and efficacious as an existing device;</p> <p>23 were you aware of that?</p> <p>24 MS. HELM: Object to the form.</p> <p>25 A. No, I didn't know those exact words.</p>	<p style="text-align: right;">Page 40</p> <p>1 MS. HELM: Object to the form.</p> <p>2 A. I would think they would have done proper study</p> <p>3 of the device before they put it on the market.</p> <p>4 Q. (BY MR. ARBON) Has any --</p> <p>5 A. Especially nowadays.</p> <p>6 Q. Any Bard rep or any representative of Bard ever</p> <p>7 informed you that in fact there is no level one</p> <p>8 randomized clinical study that demonstrates the</p> <p>9 efficacy of their filters in preventing, with regard</p> <p>10 to the mortality?</p> <p>11 MS. HELM: Object to the form.</p> <p>12 A. I don't recall talking about level one data</p> <p>13 and -- I assume you mean, like, a randomized double</p> <p>14 blind study?</p> <p>15 Q. (BY MR. ARBON) Yes, sir.</p> <p>16 A. I'm not familiar if that product's had that or</p> <p>17 not. I know those are difficult studies.</p> <p>18 Q. Would you expect that Bard would have performed</p> <p>19 sufficient clinical studies to establish the safety</p> <p>20 and long-term efficacy of their filter before they</p> <p>21 sold it?</p> <p>22 MS. HELM: Object to the form.</p> <p>23 A. I would think they would have done proper</p> <p>24 studies before they did -- put that on the market.</p> <p>25 Q. (BY MR. ARBON) If you were aware that no</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. (BY MR. ARBON) Did you know that the -- do you</p> <p>2 have any idea of what device Bard utilized as the</p> <p>3 predecessor device for the G2 in seeking FDA</p> <p>4 approval?</p> <p>5 A. No, I wouldn't know that.</p> <p>6 MS. HELM: Object to form.</p> <p>7 Q. (BY MR. ARBON) Have you ever seen of or heard of</p> <p>8 the Bard Recovery filter -- have you ever heard of</p> <p>9 the Bard enter -- I'm going to have to restate.</p> <p>10 Have you ever heard of the Bard inferior vena</p> <p>11 cava Recovery filter?</p> <p>12 A. That doesn't ring a bell.</p> <p>13 Q. Okay.</p> <p>14 A. Not sure that's the right way to say that, I'm</p> <p>15 not sure.</p> <p>16 Q. When you were going through training, did you</p> <p>17 ever work with a recover, Bard Recovery filter?</p> <p>18 A. We used different filters, I can't recall the</p> <p>19 name.</p> <p>20 Q. Would you have anticipated if a Bard is</p> <p>21 marketing and representing that the G2 filter is</p> <p>22 indicated for use in the prevention of recurrent</p> <p>23 pulmonary emboli and by a permanent placement that</p> <p>24 they would have proper randomized clinical study to</p> <p>25 support that statement before they marketed it?</p>	<p style="text-align: right;">Page 41</p> <p>1 randomized clinical studies had been performed to</p> <p>2 establish that the Bard G2 filter was safe and</p> <p>3 efficacious for the -- for reducing mortality due to</p> <p>4 permanent -- pulmonary embolism, is that information</p> <p>5 that you would have liked to have had as a physician</p> <p>6 in making your decision whether to utilize the</p> <p>7 product?</p> <p>8 MS. HELM: Objection to form.</p> <p>9 A. As a doctor I would want as much information as</p> <p>10 I could to figure out risk and benefits. And I don't</p> <p>11 know what the company would think is adequate to do</p> <p>12 that, whether it's randomized study or what. But the</p> <p>13 more information I can to provide safe care, the</p> <p>14 better.</p> <p>15 (Discussion off the record.)</p> <p>16 MS. HELM: Before you hand this</p> <p>17 document to the witness, may I please see a copy</p> <p>18 of the signed protective order?</p> <p>19 MR. ARBON: The signed protective</p> <p>20 order.</p> <p>21 MS. HELM: I want a copy of the</p> <p>22 stipulated protective order entered in this case</p> <p>23 signed by the doctor.</p> <p>24 MR. NOVOTNY: I have an e-mailed</p> <p>25 version, I can show you. I can e-mail it to</p>

24 [REDACTED]

25 [REDACTED]

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Question	Percentage of 'Yes' Answers
1. How much do you like your job?	95%
2. How much do you like your supervisor?	80%
3. How much do you like your colleagues?	90%
4. How much do you like your work environment?	40%
5. How much do you like your work schedule?	80%
6. How much do you like your work tasks?	85%
7. How much do you like your work responsibilities?	98%
8. How much do you like your work conditions?	95%
9. How much do you like your work environment?	92%
10. How much do you like your work schedule?	90%
11. How much do you like your work tasks?	70%
12. How much do you like your work responsibilities?	95%
13. How much do you like your work conditions?	85%
14. How much do you like your work environment?	95%
15. How much do you like your work schedule?	10%
16. How much do you like your work tasks?	80%
17. How much do you like your work responsibilities?	90%
18. How much do you like your work conditions?	70%
19. How much do you like your work environment?	98%
20. How much do you like your work schedule?	85%
21. How much do you like your work tasks?	90%
22. How much do you like your work responsibilities?	95%
23. How much do you like your work conditions?	60%
24. How much do you like your work environment?	80%
25. How much do you like your work schedule?	60%

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<p style="text-align: right;">Page 46</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>	<p style="text-align: right;">Page 48</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 MS. HELM: Object to the form.</p> <p>21 A. You know, honestly, as a doctor, I don't -- I</p> <p>22 don't know what Bard was doing. But as a doctor,</p> <p>23 it -- it could take years to know something. I mean,</p> <p>24 we do things and it takes years for us to understand</p> <p>25 the impact.</p>
<p style="text-align: right;">Page 47</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. (BY MR. ARBON) So as a doctor do you think it</p> <p>2 would be appropriate for the manufacturer to use</p> <p>3 patients as beta test grounds for the products?</p> <p>4 MS. HELM: Object to the form.</p> <p>5 It's argumentative.</p> <p>6 A. I would expect it to be a safe product and that</p> <p>7 they would know -- they would know the anatomy and it</p> <p>8 would function like it's -- should. I mean, I assume</p> <p>9 they went through clinical trials with test patients</p> <p>10 as well, I would assume that's the process.</p> <p>11 Q. (BY MR. ARBON) If there were no clinical trials</p> <p>12 to establish the long-term safety and efficacy of</p> <p>13 the -- their optional filters, would that be</p> <p>14 information that you as a physician would like to</p> <p>15 know when you're making a decision as to whether to</p> <p>16 use the product or not?</p> <p>17 A. I think I remember you mentioned that, that</p> <p>18 they -- they used other data from a different filter.</p> <p>19 I would -- I would rely on that, that it's safe if</p> <p>20 it's on the market.</p> <p>21 Q. But you -- but if you were told -- if you had</p> <p>22 available to you information that demonst -- that No.</p> <p>23 1, that long-term clinical trials had not been</p> <p>24 performed to establish the long-term safety and</p> <p>25 efficacy of the filter system, is that information</p>

<p style="text-align: right;">Page 50</p> <p>1 you would like to have?</p> <p>2 MS. HELM: Object to the form.</p> <p>3 A. I would -- as much information as how dangerous</p> <p>4 a product is, that would be good to have.</p> <p>5 Q. (BY MR. ARBON) All right.</p> <p>6 (Exhibit No. 2112, marked for identification.)</p> <p>7 Q. Hand you what I've marked now as Exhibit 2112 to</p> <p>8 your deposition. Which begins with the Bates No.</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>	<p style="text-align: right;">Page 52</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 (Exhibit No. 2113, marked for identification.)</p> <p>23 Q. Hand you what's been marked as 211 -- Exhibit</p> <p>24 2113 to your deposition. It is a Bard document</p> <p>25 beginning with Bates No. BPVE0101752806; do you see</p>
<p style="text-align: right;">Page 51</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>	<p style="text-align: right;">Page 53</p> <p>1 that document, sir?</p> <p>2 A. Yes.</p> <p>3 Q. If you would turn to Page 18.</p> <p>4 (Witness complies.)</p> <p>5 Q. Are you familiar with trending studies, where</p> <p>6 you look for trends in products?</p> <p>7 A. Okay.</p> <p>8 Q. Okay.</p> <p>9 A. I'm not an expert.</p> <p>10 Q. All right. But you understand the concept of</p> <p>11 comparing products together to see if there are any</p> <p>12 trends that develop?</p> <p>13 A. That sounds reasonable.</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>

<p style="text-align: right;">Page 54</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>	<p style="text-align: right;">Page 56</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>
<p style="text-align: right;">Page 55</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>	<p style="text-align: right;">Page 57</p> <p>1 [REDACTED]</p> <p>2 A. More information about the product is definitely</p> <p>3 better.</p> <p>4 Q. Doctor, have you ever seen any of the</p> <p>5 advertising related to the G2 filters or their</p> <p>6 informational brochures?</p> <p>7 A. Possibly.</p> <p>8 (Exhibit No. 2114, marked for identification.)</p> <p>9 Q. I'm going to kind of take a side trip. When you</p> <p>10 were placing the G2 filter in Ms. Kruse, did you have</p> <p>11 an expectation as to how long she was going to have</p> <p>12 that filter?</p> <p>13 A. Permanently, unless it needed to be removed.</p> <p>14 Q. So your intent was to use it as a permanent</p> <p>15 filter?</p> <p>16 A. Correct.</p> <p>17 Q. And that was something Bard told you was</p> <p>18 perfectly appropriate for their product, right?</p> <p>19 MS. HELM: Object to the form.</p> <p>20 A. Permanent option is listed on their package</p> <p>21 insert.</p> <p>22 Q. (BY MR. ARBON) Let me rephrase.</p> <p>23 From the information you were provided by Bard,</p> <p>24 did you know whether a permanent use of the G2 was</p> <p>25 one of the indicated uses?</p>

<p style="text-align: right;">Page 58</p> <p>1 A. Yes, most of these retrievable filters are</p> <p>2 permanent and retrievable.</p> <p>3 Q. I've now marked exhibit, and I'm not sure I've</p> <p>4 got number, 2114, to your deposition, which is again,</p> <p>5 begins with Bard Bates No BPV170100142912?</p> <p>6 MS. HELM: Can you tell me which</p> <p>7 number this is on the list of documents that you</p> <p>8 said you were going to use with this deposition,</p> <p>9 I don't see it on there.</p> <p>10 MR. NOVOTNY: What's your drop</p> <p>11 dead time to be done by?</p> <p>12 THE WITNESS: Don't have one,</p> <p>13 but --</p> <p>14 MR. NOVOTNY: Okay.</p> <p>15 THE WITNESS: -- I do have</p> <p>16 children at home.</p> <p>17 MR. ARBON: Having said that, I'll</p> <p>18 do my very best to pick up the pace.</p> <p>19 MS. HELM: And I get 50 percent of</p> <p>20 the time.</p> <p>21 MR. ARBON: No, I understand.</p> <p>22 THE WITNESS: Six o'clock would be</p> <p>23 preferable, if reasonable.</p> <p>24 (Discussion off the record.)</p> <p>25 MR. ARBON: I apologize, Counsel,</p>	<p style="text-align: right;">Page 60</p> <p>1 filter had more of a tendency to cause complications</p> <p>2 than its -- than its Recovery filter?</p> <p>3 MS. HELM: Object to the form.</p> <p>4 A. Say that one more time.</p> <p>5 Q. (BY MR. ARBON) Yeah. Does it surprise you to</p> <p>6 see that Bard had data that demonstrated the G2</p> <p>7 filter that you implanted in Ms. Kruse had more --</p> <p>8 higher complication rate concerning migration, tilt</p> <p>9 and perforation, than its predecessor the Recovery</p> <p>10 filter?</p> <p>11 MS. HELM: Object to the form.</p> <p>12 A. I wouldn't have known what they had at the time.</p> <p>13 Q. (BY MR. ARBON) And I'm not asking you about at</p> <p>14 the time, because I know you didn't have that</p> <p>15 information. You had no such information --</p> <p>16 A. No.</p> <p>17 Q. -- when you chose the G2, did you?</p> <p>18 A. Right, correct.</p> <p>19 Q. If you had that information when you were making</p> <p>20 decisions as to what to implant, do you know if you</p> <p>21 would have chosen that G2?</p> <p>22 MS. HELM: Object to the form.</p> <p>23 A. I would have definitely looked at the risk and</p> <p>24 benefits if there was more information.</p> <p>25 Q. (BY MR. ARBON) And if Bard's data is correct</p>
<p style="text-align: right;">Page 59</p> <p>1 I thought it was on the list.</p> <p>2 THE WITNESS: Give it back?</p> <p>3 (Witness handing document to Mr. Arbon.)</p> <p>4 Q. (BY MR. ARBON) Go back to the prior exhibit,</p> <p>5 Doctor. When you were using the G2 product, did you</p> <p>6 have an understanding from Bard that the G2 was</p> <p>7 designed to resist migration?</p> <p>8 MS. HELM: Object to the form.</p> <p>9 A. I don't recall ever being told that it cannot</p> <p>10 migrate.</p> <p>11 Q. (BY MR. ARBON) And I think the question is a</p> <p>12 little different.</p> <p>13 A. Okay.</p> <p>14 Q. Were you ever told that it was an improvement of</p> <p>15 other filters that would migrate less?</p> <p>16 MS. HELM: Object to the form.</p> <p>17 A. I don't recall that.</p> <p>18 Q. Were you ever told that it would tilt less and</p> <p>19 improve centering?</p> <p>20 MS. HELM: Object to the form.</p> <p>21 A. I don't recall that either.</p> <p>22 Q. (BY MR. ARBON) Does it surprise you to see that</p> <p>23 in -- as of November of 2008, which would have been</p> <p>24 about nine months before you used the G2 filter in</p> <p>25 Ms. Kruse, that Bard had data indicating that that G2</p>	<p style="text-align: right;">Page 61</p> <p>1 that the G2 prevented a higher risk of migration, a</p> <p>2 higher risk of perforation and a higher risk of tilt,</p> <p>3 do you think you would have chosen that if that</p> <p>4 information would have been available to you?</p> <p>5 MS. HELM: Objection to the form.</p> <p>6 A. Now, you made a big claim, so I assume that</p> <p>7 claim is correct, you know, of these higher</p> <p>8 percentages. And that would be true in every case.</p> <p>9 So, assuming that's a correct statement, the -- yeah,</p> <p>10 I would want to know if one product had different</p> <p>11 numbers relative to another product.</p> <p>12 Q. (BY MR. ARBON) Well, specific to the G2 numbers</p> <p>13 that I've shown you. If, assume for me those that,</p> <p>14 that data that Bard gave us is accurate --</p> <p>15 A. Okay.</p> <p>16 Q. -- and you had that information back in --</p> <p>17 A. Right.</p> <p>18 Q. -- 2009 when you were making the decision to put</p> <p>19 this G2 into Ms. Kruse, would that type of data</p> <p>20 affected that decision?</p> <p>21 MS. HELM: Object to the form.</p> <p>22 A. I would have definitely used that information</p> <p>23 and whatever else to make a decision.</p> <p>24 Q. (BY MR. ARBON) Okay. And had you had the</p> <p>25 benefit of that information, you may have chosen a</p>



<p style="text-align: right;">Page 62</p> <p>1 device other than a G2; is that true?</p> <p>2 MS. HELM: Object to the form.</p> <p>3 A. It's possible.</p> <p>4 Q. (BY MR. ARBON) Let's go to the implant, Doctor.</p> <p>5 A. Because then I wouldn't be meeting with you.</p> <p>6 MS. HELM: I got to move to strike</p> <p>7 that off the record.</p> <p>8 THE WITNESS: That's fine. I'm</p> <p>9 not sure how to answer that.</p> <p>10 (Discussion off the record.)</p> <p>11 (Exhibit No. 2115, marked for identification.)</p> <p>12 Q. (BY MR. ARBON) I'm going to hand you what I've</p> <p>13 marked as 2115, Doctor, and ask you if you recognize</p> <p>14 that document?</p> <p>15 A. Yes, 2115.</p> <p>16 Q. And is there a Bates number at the bottom of</p> <p>17 that page?</p> <p>18 A. There's a number.</p> <p>19 Q. Okay. Can you read that for me.</p> <p>20 MS. HELM: You can just read --</p> <p>21 A. 00288.</p> <p>22 MS. HELM: That's fine.</p> <p>23 Q. (BY MR. ARBON) Okay.</p> <p>24 A. Okay.</p> <p>25 Q. And do you recognize that document, sir?</p>	<p style="text-align: right;">Page 64</p> <p>1 preferably below the renal vein unless it needs to be</p> <p>2 placed above.</p> <p>3 But in her case, it was below the renal veins</p> <p>4 and it seemed to deploy well by x-ray. And then when</p> <p>5 the procedure was done, she seemed to do well post</p> <p>6 procedure.</p> <p>7 Q. Do you have the I -- instructions for use there,</p> <p>8 Doctor, in front of you?</p> <p>9 MR. NOVOTNY: Number 2109.</p> <p>10 A. 2109, yes, I have that.</p> <p>11 Q. (BY MR. ARBON) All right. And Exhibit 2109,</p> <p>12 instruction for use, was the procedure that you</p> <p>13 performed to implant the G2 filter on Ms. Kru -- in</p> <p>14 Ms. Kruse on July 8th of 2009, did you follow the</p> <p>15 procedures outlined by those instructions for use?</p> <p>16 A. I believe so.</p> <p>17 Q. All right. One of the things that it says is</p> <p>18 you need to know if her inferior vena cava diameter</p> <p>19 was correct; is that right?</p> <p>20 A. That's correct.</p> <p>21 Q. And --</p> <p>22 A. And hers was.</p> <p>23 (Exhibit No. 2116, marked for identification.)</p> <p>24 Q. I hand you Exhibit 2116, which is part of a</p> <p>25 series of images under RAD00011. And are you</p>
<p style="text-align: right;">Page 63</p> <p>1 A. Yes.</p> <p>2 Q. And what is that?</p> <p>3 A. That is the hospital record for deploying a G2</p> <p>4 filter.</p> <p>5 Q. Is that your record, is that your dictation?</p> <p>6 A. Correct, yes.</p> <p>7 Q. And that's for the deployment of the filter that</p> <p>8 you placed in Ms. --</p> <p>9 A. Kruse.</p> <p>10 Q. -- Kruse; is that correct?</p> <p>11 A. That's correct.</p> <p>12 Q. And when you did you place the filter?</p> <p>13 A. Procedure was 7/8/2009.</p> <p>14 Q. Can you describe the procedure for placing the</p> <p>15 filter into Ms. Kruse for me.</p> <p>16 A. In general, you get consent from the patient.</p> <p>17 For this case, I reviewed a CT scan of the abdomen to</p> <p>18 know where the renal veins were located and where</p> <p>19 the -- and the size of the IVC.</p> <p>20 And then you discuss the risks and benefits with</p> <p>21 the patient. And if they agree, then the patient's</p> <p>22 placed on their back and a -- the neck is cleaned in</p> <p>23 the appropriate manner and then all the procedural</p> <p>24 steps are performed, where using x-ray device</p> <p>25 fluoroscopy. And then the filter is placed,</p>	<p style="text-align: right;">Page 65</p> <p>1 familiar with that image, sir?</p> <p>2 A. That looks like a CT image that would be from</p> <p>3 Ms. Kruse based on the labeling.</p> <p>4 Q. And based on labeling, can you tell what date</p> <p>5 that was taken?</p> <p>6 A. July 7, 2009.</p> <p>7 Q. All right. And that would have been --</p> <p>8 A. That would be one day prior to the procedure.</p> <p>9 Q. All right. And there's a measurement in the</p> <p>10 middle of that CT scan; do you see that?</p> <p>11 A. That's correct.</p> <p>12 Q. And what's that?</p> <p>13 A. That says 21.4 millimeters.</p> <p>14 Q. And what does that reference?</p> <p>15 A. The size of the IVC at that level.</p> <p>16 Q. All right. Is that the level at which the</p> <p>17 filter was going to be placed?</p> <p>18 A. Approximately.</p> <p>19 Q. And is that the purpose of making that</p> <p>20 measurement?</p> <p>21 A. Correct.</p> <p>22 Q. Can I get you to hold that up so the camera can</p> <p>23 see it, sir.</p> <p>24 (Witness complies.)</p> <p>25 Q. Kind of like teaching school. You don't need to</p>

<p style="text-align: right;">Page 66</p> <p>1 hold them both, just the image.  2 (Witness complies.)  3 Q. And can you point to -- so her caval diameter  4 was appropriate to the filter, there's no doubt?  5 MS. HELM: Object to the form.  6 A. Correct.  7 Q. (BY MR. ARBON) Was her caval diameter  8 appropriate for the G2 filter, sir?  9 A. I believe so.  10 Q. And then, once you placed the filter, did you do  11 any additional imaging?  12 A. The fluoroscopic imaging to show that it was  13 located in the IVC.  14 Q. I'll be with you in a second, sir.  15 I'm going to hand you what I've marked as  16 Exhibit 2117, sir, and ask if you recognize these  17 images?  18 (Exhibit No. 2117, marked for identification.)  19 Q. Do you recognize those images, sir?  20 A. I believe these would be from the July 8, 2009  21 procedure.  22 Q. All right. What types of images are we looking  23 at here?  24 A. These are fluoroscopic images that are printed  25 on paper.</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. (BY MR. ARBON) Let me ask you, Doctor, based on  2 your review of this imaging, your review of your  3 report, was the G2 filter that was placed in  4 Ms. Kruse on July 8th of 2009 placed properly?  5 MS. HELM: Object to the form.  6 A. I believe the filter I placed was appropriate in  7 position and the procedure went well.  8 Q. (BY MR. ARBON) What was your intent in placing  9 that filter?  10 A. To -- to properly place the filter to avoid any  11 complications she might have later.  12 Q. And I think you told me it was your intention  13 that that filter remain as a permanent filter?  14 MS. HELM: Object to the form.  15 A. That was -- that was the -- that was the plan.  16 Q. (BY MR. ARBON) Doctor, what was your plan for  17 that filter? When you were you planning to retrieve  18 it when you put it in?  19 A. I wasn't planning on retrieving it unless it  20 needed to be retrieved.  21 Q. Once you place that filter, Doctor, what was  22 your expectation as to whether it would -- where it  23 would remain as long as in her body?  24 A. I would expect it to remain in the same  25 location. I would prefer it to remain in the same</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. All right. Not always very easy to see.  2 Can you make out from these images, sir, the  3 location of the IVC filter?  4 A. Barely.  5 Q. All right. If I give you this marker, could you  6 circle it for me?  7 A. I think so.  8 Q. All right.  9 (Witness complies.)  10 A. Approximately in the middle of the spine.  11 Q. All right. And at what level vertebrae is that?  12 A. Assuming 12 ribs, L3, approximately.  13 Q. Is that proper placement?  14 A. In most cases, that's true.  15 Q. And for Ms. Kruse?  16 A. I believe it was appropriate.  17 Q. And is the filter deployed?  18 A. The filter is deployed and it's without tilting  19 and at that location.  20 Q. So she has a proper -- properly implanted and  21 deployed filter based upon your review of the imaging  22 and your recollection of the procedure based upon  23 your report?  24 MS. HELM: Object to the form.  25 A. Correct.</p>	<p style="text-align: right;">Page 69</p> <p>1 location.  2 Q. In your review of that IFU, does the  3 instructions for use for the G2 filter, say anything  4 about a need to remove the filter as soon as the risk  5 of a pulmonary embolism subsides in the patient?  6 MS. HELM: Object to the form.  7 A. Say that again.  8 Q. (BY MR. ARBON) Sure. Does the instructions for  9 use related to the G2 filter that is marked as an  10 exhibit and that you've reviewed, say anything about  11 the need to remove the G2 filter as soon as the risk  12 of a pulmonary embolism subsides in the patient?  13 A. The G2 filter can be a permanent or -- or  14 retrievable filter.  15 Q. Was it your understanding that this filter would  16 not present any greater risk over time --  17 MS. HELM: Object to the form.  18 Q. (BY MR. ARBON) To the patient?  19 MS. HELM: Same objection.  20 A. The filter was not -- correct, if I understood  21 that right, the filter would not cause her any more  22 risk.  23 Q. (BY MR. ARBON) If you had known and it had been  24 explained to you that the longer a G2 filter was in  25 dwelling within a patient, the greater the risk that</p>

<p style="text-align: right;">Page 70</p> <p>1 it would cause some complication, would that have  2 been information that may have altered your plan for  3 this patient?  4 MS. HELM: Object to the form.  5 A. Um, let's see, if a G2 filter long-term risk was  6 dangerous to the patient, that would change -- could  7 possibly change what I did.  8 Q. (BY MR. ARBON) If you had known at the time you  9 were choosing the G2 and placing it into Ms. Kruse  10 that the longer the G2 was in place, the more the  11 risk of perforation, tilt, migration and fracture,  12 that those risks would increase, would that have  13 altered your plan for her?  14 MS. HELM: Object to the form.  15 A. I believe so.  16 Q. (BY MR. ARBON) Would you have -- how? In what  17 way?  18 A. If you -- if the -- if the filter -- let me see  19 how to say this accurately. If complications were to  20 come from the filter, retrieval may be appropriate.  21 Q. If you had thought that the long term -- the  22 longer the filter remained in her body, the more risk  23 there was of a migration, fracture, tilt or  24 perforation, you would -- is it reasonable to say  25 that you might have considered retrieval as opposed</p>	<p style="text-align: right;">Page 72</p> <p>1 perhaps caused you to maybe want to monitor her  2 closely or remove the filter?  3 MS. HELM: Object to the form.  4 A. They're different options for patient care.  5 Q. (BY MR. ARBON) When was the next time that  6 Ms. Kruse -- you came in contact with Ms. Kruse?  7 A. When she represented for retrieval.  8 Q. And do you know when that was?  9 A. No.  10 (Exhibit No. 2118, marked for identification.)  11 Q. Let me show you what I've marked as Exhibit 2118  12 to your deposition, sir, and ask you if you recognize  13 that document?  14 A. This is the report of the attempt at IVC  15 retrieval dated April 7, 2011.  16 Q. And can you explain to me what -- what was the  17 purpose of your performing this procedure on  18 Ms. Kruse on April 7th of 2011?  19 A. To retrieve the filter that had migrated  20 caudally and tilted.  21 Q. Okay. And why were you trying to retrieve that  22 filter?  23 A. Because it had migrated caudally.  24 Q. Okay. And I guess what I'm saying, what is it  25 about the fact that it migrated that caused you to</p>
<p style="text-align: right;">Page 71</p> <p>1 to a permanent placement?  2 MS. HELM: Object to the form.  3 A. At the time, I was just thinking it was a  4 permanent filter would stay where it was.  5 Q. (BY MR. ARBON) And I understand that. And  6 that's what was represented to you by the IFU and  7 other sources, correct?  8 A. Okay.  9 Q. Is that true?  10 MS. HELM: Object to the form.  11 A. The filter could be a permanent filter and do  12 well.  13 Q. (BY MR. ARBON) All right. And what I'm asking  14 you I guess is hypothetical. But hypothetically, if  15 the data had been made available for you where you  16 had been informed that the longer a G -- the longer  17 the in-dwell time or the implanting time of a G2  18 within the human body, the more you increase the risk  19 of a migration, perforation, tilt or other  20 complication, do you think that would have caused you  21 to alter your use of it as a permanent filter?  22 MS. HELM: Object to the form.  23 A. If the filter were unsafe, that might -- that  24 would change the way I managed the patient.  25 Q. (BY MR. ARBON) Would that information have</p>	<p style="text-align: right;">Page 73</p> <p>1 believe it should be retrieved?  2 MS. HELM: Object to the form.  3 A. I believe she had some symptoms of pulling  4 sensation.  5 Q. (BY MR. ARBON) Okay. What did you do to attempt  6 to retrieve the filter?  7 A. With similar technique as implanting it, using  8 instead a Recovery Cone device to snare the filter  9 and remove it.  10 Q. So you made an incision in her neck, did you --  11 A. Made a -- you could call it an incision, it's  12 more of a needle puncture.  13 Q. All right. And you went through the jugular  14 vein to try to reach the filter?  15 A. Correct.  16 Q. What device were you using to try to reach the  17 filter initially?  18 A. The Recovery Cone device.  19 Q. And if you look, sir, again at the instruction  20 for use, is that what Bard recommended you do to try  21 to retrieve the G2 filter?  22 A. Yes, I believe so.  23 Q. And in fact, did Bard state on numerous  24 occasions, remove the G2 filter using the Recovery  25 Cone Removal System only?</p>

<p style="text-align: right;">Page 74</p> <p>1 A. I saw that.</p> <p>2 Q. Okay. And that's what you were attempting to</p> <p>3 do; is that correct?</p> <p>4 A. That's correct.</p> <p>5 Q. Were you trying to follow the instructions for</p> <p>6 use that Bard had provided for recovering a G2</p> <p>7 filter?</p> <p>8 MS. HELM: Object to the form.</p> <p>9 A. I was recovering the way I had been trained.</p> <p>10 Q. (BY MR. ARBON) Did you think when you attempted</p> <p>11 the recovery that you would be successful?</p> <p>12 A. I was hoping so.</p> <p>13 Q. Would you have attempted it if you did not</p> <p>14 believe you had any chance to succeed?</p> <p>15 A. No.</p> <p>16 Q. Why were you unable to retrieve that filter?</p> <p>17 A. It had tilted so that the cone could not engage</p> <p>18 the top part of the filter.</p> <p>19 Q. And when you say, "it had tilted," what is</p> <p>20 tilted?</p> <p>21 A. The IVC filter.</p> <p>22 Q. And when you found you could not engage the,</p> <p>23 the -- what portion of the filter were you going</p> <p>24 after?</p> <p>25 A. The top part.</p>	<p style="text-align: right;">Page 76</p> <p>1 A. I believe so.</p> <p>2 Q. And so again, in following the instructions for</p> <p>3 use and conforming your retrieval technique to the</p> <p>4 techniques recommended by Bard, were you successful</p> <p>5 in retrieving her filter?</p> <p>6 A. I was not successful in retrieving her filter</p> <p>7 the way I was trained.</p> <p>8 (Exhibit No. 2119, marked for identification.)</p> <p>9 Q. I'm going to hand you what I've marked as</p> <p>10 Exhibit 2119, sir. And just ask if you recognize</p> <p>11 those images?</p> <p>12 A. They are x-rays of the IVC filter.</p> <p>13 (Witness indicates.)</p> <p>14 Q. All right. Again, I'm going to give you the</p> <p>15 blue pen back, sir. And if I could, could you mark</p> <p>16 for me where the IVC filter appears in these images.</p> <p>17 MR. NOVOTNY: There's another</p> <p>18 page, Doctor.</p> <p>19 THE WITNESS: Okay.</p> <p>20 (Witness complies.)</p> <p>21 A. There's two pictures, one from the front, one</p> <p>22 from the side of the filter.</p> <p>23 (Witness indicates.)</p> <p>24 Q. (BY MR. ARBON) And do you recognize, in the</p> <p>25 context we're discussing this of the retrieval of</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. All right. When you could not engage the top of</p> <p>2 that filter, what did you do?</p> <p>3 A. Tried placing a wire next to the filter and</p> <p>4 engaging again.</p> <p>5 Q. And was that procedure successful?</p> <p>6 A. No.</p> <p>7 Q. Now, is that procedure of placing a wire next to</p> <p>8 the filter to engage again something that was</p> <p>9 included in Bard's instructions for how to retrieve a</p> <p>10 filter?</p> <p>11 A. I don't know, that's --</p> <p>12 Q. You have those instructions in front of you,</p> <p>13 sir.</p> <p>14 A. I would not know that answer, I would have to...</p> <p>15 There's a section of optional procedure for</p> <p>16 filter removal, but I would have to continue to read</p> <p>17 to figure out what that involves.</p> <p>18 Q. Now, if you would take a minute and do it for</p> <p>19 me, sir, I hate to waste your time, but it's</p> <p>20 important.</p> <p>21 (Witness complies.)</p> <p>22 A. Bottom of Page 4, it says if, if it is difficult</p> <p>23 to align the cone, a guidewire could be used.</p> <p>24 Q. Okay. And is that what you were attempting to</p> <p>25 do?</p>	<p style="text-align: right;">Page 77</p> <p>1 Ms. Kruse, the positioning in these -- recognize</p> <p>2 these images?</p> <p>3 A. Yes, this is a when she would have represented</p> <p>4 for removal or prior to the removal.</p> <p>5 Q. Is that filter that's depicted in the images --</p> <p>6 MS. HELM: I'm going to just</p> <p>7 object that it's not clear from the documents</p> <p>8 what they are, but you can go on.</p> <p>9 Q. (BY MR. ARBON) Do you remember seeing these</p> <p>10 images in the past, now that you've had a chance to</p> <p>11 look at them, do you not?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 A. After being notified with the case, I looked at</p> <p>14 her medical records and she had an x-ray taken. And</p> <p>15 this is labeled Carol Kruse at the top with no date.</p> <p>16 Q. (BY MR. ARBON) Okay. Is the filter that we --</p> <p>17 as we see it in this exhibit, which is 2119 --</p> <p>18 A. Okay.</p> <p>19 Q. -- a properly positioned filter?</p> <p>20 A. Not, not -- not in my opinion --</p> <p>21 Q. Okay.</p> <p>22 A. -- for Ms. Kruse.</p> <p>23 Q. Do you know if this filter would be efficacious</p> <p>24 in preventing pulmonary embolism from traveling</p> <p>25 through the vena cava --</p>



<p style="text-align: right;">Page 78</p> <p>1 MS. HELM: Object to form.</p> <p>2 Q. (BY MR. ARBON) As its positioned?</p> <p>3 A. A filter at this location could still stop a</p> <p>4 blood clot in the leg from going to the lungs.</p> <p>5 Q. Do you know if it is, it is capable of stopping</p> <p>6 pulmonary embolism as designed, once it reached this</p> <p>7 position?</p> <p>8 A. It still could.</p> <p>9 Q. Okay. But do you know if it would?</p> <p>10 MS. HELM: Object to the form,</p> <p>11 calls for speculation.</p> <p>12 A. My impression would, it should.</p> <p>13 Q. (BY MR. ARBON) Was this the medically desired</p> <p>14 result you had when you placed that G2 filter as a</p> <p>15 permanent filter?</p> <p>16 A. No, I prefer it to stay where it was located.</p> <p>17 Q. How many different approaches or attempts did</p> <p>18 you make to try to retrieve her filter, sir; do you</p> <p>19 recall?</p> <p>20 A. At least two.</p> <p>21 Q. And who was present with you when you were</p> <p>22 making those attempts?</p> <p>23 MS. HELM: Object to the form,</p> <p>24 it's been asked and answered.</p> <p>25 A. There would have been an x-ray tech and I recall</p>	<p style="text-align: right;">Page 80</p> <p>1 in the instructions for use for the product; is that</p> <p>2 fair?</p> <p>3 MS. HELM: Object to the form.</p> <p>4 A. It -- I don't see it in this G2 filter insert</p> <p>5 and it's, but it's a known medical -- or it -- it's a</p> <p>6 standard of care in some facilities to do that.</p> <p>7 Q. (BY MR. ARBON) And in light of the objection,</p> <p>8 let me ask it this way: Is this a loop technique</p> <p>9 that you had mentioned earlier?</p> <p>10 A. That's what I've called it, uh-huh.</p> <p>11 Q. The loop technique that you're referencing, is</p> <p>12 that a technique that is included as a method for</p> <p>13 retrieving a Bard G2 filter in the instructions for</p> <p>14 use provided by Bard?</p> <p>15 A. I don't see it in this paperwork, it's a general</p> <p>16 use for filters, retrievable filters in general.</p> <p>17 Q. And it was -- was that technique discussed by</p> <p>18 you and the Bard representative at the time of</p> <p>19 Ms. Kruse's failed retrieval attempt?</p> <p>20 MS. HELM: Object to the form.</p> <p>21 A. As an option if I wanted to proceed.</p> <p>22 Q. (BY MR. ARBON) Okay. And did you proceed with</p> <p>23 that technique?</p> <p>24 A. No, I chose not to.</p> <p>25 Q. And what did you do instead?</p>
<p style="text-align: right;">Page 79</p> <p>1 a Bard rep there, I don't remember his name --</p> <p>2 Q. (BY MR. ARBON) Do you recall any --</p> <p>3 A. But don't remember his name.</p> <p>4 Q. Do you recall any of the conversations you had</p> <p>5 with the Bard rep during your attempts to retrieve</p> <p>6 this filter?</p> <p>7 A. I remember after we were unsuccessful, there's a</p> <p>8 technique where you can use a wire to reposition the</p> <p>9 filter and we discussed that, but I chose not to</p> <p>10 pursue that and instead refer the patient.</p> <p>11 Q. Okay. First of all, the technique you were</p> <p>12 discussing, was it a technique being discussed by the</p> <p>13 Bard rep or was it a technique you were asking him</p> <p>14 about or if you understand the difference?</p> <p>15 A. A technique that he knew about and that I seen</p> <p>16 in literature before and heard about.</p> <p>17 Q. And was that a technique that would be any of</p> <p>18 the techniques that you read in the instructions for</p> <p>19 use just now?</p> <p>20 A. I would have to look again.</p> <p>21 (Witness reading document.)</p> <p>22 A. I don't think that technique's at the end of the</p> <p>23 document, even though it's known in the literature.</p> <p>24 Q. But what was being recommended and discussed</p> <p>25 with the Bard rep was a technique that's not included</p>	<p style="text-align: right;">Page 81</p> <p>1 A. Referred the patient.</p> <p>2 Q. All right. And what do you mean by, "referred</p> <p>3 the patient"?</p> <p>4 A. Planned for her to be seen at Lincoln for her</p> <p>5 removal.</p> <p>6 Q. And Lincoln, where in Lincoln?</p> <p>7 A. I believe Bryan Hospital, but I would have to</p> <p>8 check for sure. That's usually where patients are</p> <p>9 referred.</p> <p>10 Q. Okay. And you're saying you actually made an</p> <p>11 arrangement for her to be referred to a particular</p> <p>12 physician at that hospital?</p> <p>13 A. Yeah, the notes from the technician are</p> <p>14 documented on, in her chart.</p> <p>15 Q. Is the technician the R T?</p> <p>16 A. Correct.</p> <p>17 (Exhibit No. 2120, marked for identification.)</p> <p>18 Q. Who would you have referred her to at Bryan</p> <p>19 Hospital in Lincoln?</p> <p>20 A. They have an interventional radiologist there.</p> <p>21 Q. Do you know his name, who it was you would have</p> <p>22 made the referral to?</p> <p>23 A. Well, there's -- well, there's two different</p> <p>24 facilities so there's St. Elizabeth and there's Bryan</p> <p>25 Hospital and there's an interventionist in each one.</p>

<p style="text-align: right;">Page 82</p> <p>1 Q. So you didn't make a recommendation to a 2 specific person, you were recommending a facility? 3 A. I would have to -- I would have to look at the 4 medical record. 5 Q. Okay. Well, let me hand you what I marked as 6 2120 and ask you if that's the record you're talking 7 about? 8 A. I think there's another documentation as well, 9 but this one did -- did seem to reflect that we had 10 offered her two choices, Grand Island where there's 11 an internationalist and actually, two 12 internationalist, and also Lincoln. 13 I think there's another handwritten 14 documentation from the -- from the tech that talks 15 about Ms. Kruse had some social issues so she wasn't 16 able to. 17 Q. Well, is this a note from the tech, sir? 18 A. No, there's another -- there's the tech but 19 there's -- 20 Q. And it references that -- 21 A. There's another note. 22 Q. Just want to reference she scheduled -- moving 23 to Lincoln in July, will contact her doctor in 24 Lincoln. 25 A. No, there's another one that should say that the</p>	<p style="text-align: right;">Page 84</p> <p>1 Lincoln, she had to try and get a job, did you tell 2 her that that would be contraindicated that she 3 needed to get that filter out immediately or 4 urgently? 5 A. I believe that, yes, the wording would be that 6 she was encouraged to not delay. 7 Q. Okay. And I have been through the record, 8 Doctor -- have you found it? 9 A. There we go, yes. 10 So it says, "Called Carol Kruse," so this would 11 have been the tech, because I remember specifically 12 telling her that since this was a special case, that 13 she needed to document well, which we're all trained 14 to do and I guess in this case, it was true. 15 So it says, "Call Carol Kruse and spoke to her 16 about IVC filter and when she was going to have had 17 removed in Lincoln and that she stated she would call 18 me when she moves to Lincoln and she would schedule 19 it to see." 20 And I told the tech to make sure she documented 21 well and I see at the bottom she wrote, "Patient was 22 told not to delay removal and scheduling depends on 23 her choice," I think is the word. 24 Q. Okay. 25 A. So that's the x-ray tech, like you said. So</p>
<p style="text-align: right;">Page 83</p> <p>1 tech is or the -- that she was -- I think there's 2 another note. I could be wrong, but I believe 3 there's another note. 4 MS. HELM: If you have a come -- 5 if someone has a complete -- 6 A. This one says, "Obviously, it was offered to her 7 to go to Grand Island to have it removed and she 8 refused due to her work schedule." I remember 9 communications about that. And she was moving to 10 Lincoln and so there were some -- where she was 11 moving and living and when she could get off of work. 12 And we offered -- and there should be a note 13 that we encouraged -- that she was recommended to do 14 it sooner rather than later, there as note in the 15 chart somewhere. 16 (Exhibit No. 2121, marked for identification.) 17 Q. (BY MR. ARBON) I'll hand you, Doctor, what I've 18 marked as Exhibit 2121. 19 A. And that -- 20 Q. And ask you if you recognize those notes? 21 A. Yeah, that's my note saying basically the risks 22 were discussed before we started the procedure and 23 had complications that could occur and that the 24 retrieval was unsuccessful. 25 Q. Okay. Once she stated that she was moving to</p>	<p style="text-align: right;">Page 85</p> <p>1 basically, yeah, she was -- we were unsuccessful and 2 so she was referred to a tertiary or to a different 3 facility. 4 MS. HELM: Can we go off the 5 record and get copies of that? 6 MR. NOVOTNY: Let's go off the 7 record first and we talk about it. 8 VIDEOGRAPHER: We are off the 9 video record at 1604. 10 (Recess was taken.) 11 (Exhibit No. 2122, marked for identification.) 12 VIDEOGRAPHER: We are back on the 13 video record at 1611, please proceed. 14 Q. 2122. Doctor, we marked as exhibit to your 15 deposition, 2122. Can you tell me what that is, 16 exactly? 17 A. Knowing that we were unsuccessful and removing 18 the filter for Carol Kruse, I thought it was 19 important that we document well our plan. And so I 20 total the tech to make sure any communication she had 21 she wrote down. And this outlines basically the plan 22 that we gave her. 23 And then the last part was that the removal 24 would be better if it was sooner rather than later 25 essentially.</p>

<p style="text-align: right;">Page 86</p> <p>1 Q. And I just want to ask you something about this  2 and I'll just tell you; we requested copies from the  3 hospital of the records and this is the first time  4 I've seen this piece of paper. So my question to you  5 is: First of all, what type of record is this?  6 A. It's part of the medical record.  7 Q. Okay. If you would look, sir, at Exhibits 21 --  8 I think it's 2120 and 2122. Now, those are  9 handwritten records --  10 A. Uh-huh, so --  11 Q. -- of the discussions you had post op from the  12 retrieval; are they not?  13 A. Let's see, so they and you can -- the  14 handwriting's the same, signature is the same, Joyce  15 Biecks (sic), Bieck, RT.  16 MR. NOVOTNY: Spell the last name  17 for us, Doctor, if you can.  18 THE WITNESS: I'm not sure how to  19 spell it.  20 MR. NOVOTNY: Understood.  21 Q. (BY MR. ARBON) Can I just see which one of these  22 is which, I'm sorry.  23 A. So these two are the same, looks like they  24 have --  25 Q. And first I need to object to, the answer is</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. And then up at the top, there's a -- got kind of  2 I'll call it a grid but there's a lined in area  3 where your notes were made, right? And it says  4 progress notes at the top?  5 A. Right. That particular one, it has lines on it,  6 correct.  7 Q. And then the same thing for 2121, it's on a same  8 form --  9 A. Correct.  10 Q. -- of paper?  11 A. And usually these are a chart, a physical chart  12 that follows the patient around during procedures.  13 Q. And I don't see any of those same markings or  14 indication on 2122, do I?  15 A. I don't see lines, but, but it's part of the  16 medical record.  17 Q. If you look -- and I understand, sir. I'm  18 really just trying to point out the differences so I  19 can try to understand.  20 If you look carefully at the copy we have, does  21 that appear to be, do you see there's lines around  22 the note, does that appear to be a piece of notepad  23 that that was written on and placed on the record?  24 A. I'm not sure what it is. The x-ray tech was  25 instructed to document well and this is the</p>
<p style="text-align: right;">Page 87</p> <p>1 nonresponsive. Don't worry about that.  2 A. Okay.  3 Q. Just so I can know what I'm talking about, 2120  4 and then 2121.  5 A. Okay, 2121 is my handwriting.  6 Q. Okay. If you would, sir, if you could just hold  7 up for the camera, 2120 and then could you hold up  8 2122, please, next to 2120.  9 (Witness complies.)  10 Q. And what I'm trying to do is compare the two  11 notes and then I'm going to ask you some questions  12 about them.  13 A. Uh-huh.  14 Q. We need to have you do that again. If you hold  15 that so the camera can focus on them for a minute.  16 (Witness complies.)  17 Q. Okay. In 2120, sir, if you look at it, that's a  18 hospital chart record; is it right?  19 A. It looks like a, it has labeling on it.  20 Q. Right. And it's got Mary Lanning Hospital on it  21 on the bottom, it says physician progress note?  22 A. Right.  23 Q. It's got her bar code for Ms. Kruse's patient  24 admission?  25 A. Correct.</p>	<p style="text-align: right;">Page 89</p> <p>1 documentation.  2 Q. The note she has says called Carol Kruse?  3 A. That's what it says.  4 Q. Carol Kruse was in the hospital, she wouldn't  5 have to have been called, would she?  6 MS. HELM: Object to the form.  7 A. No, I don't -- why would you say that?  8 Q. (BY MR. ARBON) Okay. Well, none of the other  9 notes --  10 A. Uh-huh.  11 Q. -- the rad's note --  12 A. Uh-huh.  13 Q. -- your handwritten notes --  14 A. And this was --  15 Q. -- refer to her being called. Carol was  16 called -- called Carol Kruse and spoke to her?  17 A. That's what --  18 Q. Had she already left the hospital when this call  19 was made?  20 A. This is dated 7/7/2011.  21 Q. You're absolutely right.  22 A. So yes, she was called for follow-up to --  23 'cause the tech was instructed to document well and  24 maintain her care.  25 Q. And I'm seeing it now.</p>

<p style="text-align: right;">Page 90</p> <p>1 A. Seeing what?</p> <p>2 Q. 4/7/11 is when she had her procedure?</p> <p>3 A. Correct, that was -- I believe that's what the</p> <p>4 pictures show.</p> <p>5 Q. I gotcha. So this note was added to the chart</p> <p>6 seven months after -- three months after the</p> <p>7 procedure, the failed retrieval procedure?</p> <p>8 A. Yes, she -- that's true or it seems to be.</p> <p>9 Q. Okay. So this was a follow-up some months after</p> <p>10 the retrieval?</p> <p>11 A. It appears that way, yeah.</p> <p>12 Q. Okay. I get it now, that's...</p> <p>13 A. Yeah. So that's not -- that's why it's not,</p> <p>14 probably the physical chart's not following the</p> <p>15 patient around anymore, now it's, she is contacting</p> <p>16 her by phone.</p> <p>17 Q. All right.</p> <p>18 A. So that may explain why the paper --</p> <p>19 Q. So the recommendation made at the time that you</p> <p>20 told her you could set her up at Grand Island if she</p> <p>21 wanted to have it removed at the time of the</p> <p>22 procedure, I'm looking at Exhibit 2120.</p> <p>23 A. Yes, 4/7/2011, it was recommended since we</p> <p>24 couldn't remove it, that she have it removed --</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 92</p> <p>1 unsuccessful, correct?</p> <p>2 A. My attempts were unsuccessful.</p> <p>3 Q. And so the referral you were making was to see</p> <p>4 if it could be retrieved; is that fair?</p> <p>5 A. That would -- the point was to retrieve,</p> <p>6 retrieve the filter, if possible.</p> <p>7 Q. Doctor, during the implant procedure, I'm</p> <p>8 turning your head around a little bit, how are the</p> <p>9 instruments -- how is the G2 filter kit itself</p> <p>10 handled during the surgery?</p> <p>11 A. It comes in a large box, it's unwrapped</p> <p>12 sterilely and handed to the tech. And then we lay it</p> <p>13 out, usually on two trays, sterilely.</p> <p>14 Q. Is the box itself that it's shipped in, does</p> <p>15 that come into the interventional suite?</p> <p>16 A. Yes.</p> <p>17 Q. And do you see that box when you come in?</p> <p>18 A. I see the -- when I -- yeah, I see the box.</p> <p>19 Q. Okay.</p> <p>20 A. It's opened up.</p> <p>21 Q. Do you see it open, being opened.</p> <p>22 A. Correct, yeah.</p> <p>23 Q. Is anything done to the G2 filter device, the</p> <p>24 filter, the implanting equipment, the kit itself, is</p> <p>25 anything done by any of the hospital staff to alter,</p>
<p style="text-align: right;">Page 91</p> <p>1 A. -- either in Grand Island or Lincoln. And</p> <p>2 that's documented by the tech.</p> <p>3 Q. Right, but --</p> <p>4 A. And the same, same tech that wrote a note to</p> <p>5 document the 7/7/2011 conversation.</p> <p>6 Q. Yeah. And the tech's note is, Carol was offered</p> <p>7 to go to Grand Island, right?</p> <p>8 A. And the day of 4/7, that's what we discussed</p> <p>9 with her.</p> <p>10 Q. Okay. And then there's another note three</p> <p>11 months later where you followed up to say --</p> <p>12 A. Where the tech followed up.</p> <p>13 Q. All right. Do you know if that physician,</p> <p>14 either on 4/11 or 7/11, any physician can you state</p> <p>15 that they would have been successful in retrieving</p> <p>16 that filter?</p> <p>17 MS. HELM: Object to the form.</p> <p>18 A. I wouldn't know if they would be or not.</p> <p>19 Q. (BY MR. ARBON) Can you tell me what type of</p> <p>20 procedure would have been required to retrieve that</p> <p>21 filter, either in April or July of 2011?</p> <p>22 A. No, I don't know what technique he would use.</p> <p>23 Q. The techniques that you knew about and that you</p> <p>24 were -- that are referenced in the IFU and that you</p> <p>25 were comfortable performing that day were</p>	<p style="text-align: right;">Page 93</p> <p>1 modify or change that device?</p> <p>2 A. No.</p> <p>3 Q. If you had observed a G2 filter kit, the filter</p> <p>4 itself, the implanting equipment being changed or</p> <p>5 modified, would you have used it?</p> <p>6 A. No.</p> <p>7 Q. So is it fair to say, sir, that the G2 filter</p> <p>8 that you implanted in Ms. Kruse was in the same</p> <p>9 condition as when it arrived in the box?</p> <p>10 A. Yes.</p> <p>11 Q. At the time you obtained Ms. Kruse's consent to</p> <p>12 have the filter placed, what were the risks that you</p> <p>13 discussed with her?</p> <p>14 A. The risk, we'll have to get the --</p> <p>15 MR. NOVOTNY: You want your note?</p> <p>16 THE WITNESS: Yeah, I think</p> <p>17 there's a couple of 'em.</p> <p>18 Q. (BY MR. ARBON) There are and I'm going to give</p> <p>19 you both.</p> <p>20 A. Okay. Let's see, so...</p> <p>21 Q. What I'm going to hand you, sir, are exhibits</p> <p>22 2123 and 2124.</p> <p>23 (Exhibit Nos. 2123 through 2124, marked for</p> <p>24 identification.)</p> <p>25 A. Okay. Can we have -- we have several papers</p>



<p style="text-align: right;">Page 94</p> <p>1 where we try to discuss and cover risk, four total.</p> <p>2 Q. I understand. Some of those are to do with the</p> <p>3 retrieval, correct?</p> <p>4 A. Let's see here, three of them have to do with</p> <p>5 July 8, 2009.</p> <p>6 (Discussion off the record.)</p> <p>7 Q. (BY MR. ARBON) That is exactly where I'm going,</p> <p>8 Doctor. When I had the opportunity to meet with you,</p> <p>9 you had brought up to me the issues of these consent</p> <p>10 forms, correct?</p> <p>11 A. Correct. Oh, yeah, here we go.</p> <p>12 Q. In looking at exhibit -- let me see which is</p> <p>13 here, which one is the one that has your name at the</p> <p>14 top, what number?</p> <p>15 MR. NOVOTNY: 2123.</p> <p>16 Q. (BY MR. ARBON) 2123. The other one is 24?</p> <p>17 MR. MACDONALD: Right.</p> <p>18 Q. All right. 2123 is what type of form, sir?</p> <p>19 A. 2123 is a standard hospital form for most</p> <p>20 invasive procedures.</p> <p>21 Q. All right. And what's the date that's placed on</p> <p>22 that form?</p> <p>23 A. At the top of the form says July 8, 2009.</p> <p>24 Q. And whose name appears on the first page of that</p> <p>25 form?</p>	<p style="text-align: right;">Page 96</p> <p>1 informed decision as to whether to -- the benefits of</p> <p>2 the procedure outweigh the risks?</p> <p>3 MS. HELM: Object to the form.</p> <p>4 Q. (BY MR. ARBON) Is that what the purpose of the</p> <p>5 consent is?</p> <p>6 MS. HELM: Object to form.</p> <p>7 A. The purpose is to document as best you can that</p> <p>8 the risk and benefits were covered and the patient</p> <p>9 had an opportunity to be involved.</p> <p>10 Q. (BY MR. ARBON) And just so you know, I'm not</p> <p>11 trying to necessarily play any games with you here,</p> <p>12 my understanding from our conversation, can you</p> <p>13 explain to me -- let's look at Page 2123.</p> <p>14 A. 2123, yes.</p> <p>15 Q. All right. Exhibit 2123 is also an informed</p> <p>16 consent form, correct?</p> <p>17 MS. HELM: It's the same one.</p> <p>18 A. Like 2124.</p> <p>19 Q. (BY MR. ARBON) I'm sorry, I misnumbered it.</p> <p>20 2124 is what I'm talking about. So let me start</p> <p>21 over.</p> <p>22 We have 2123 is informed consent form that has</p> <p>23 your handwritten name on it, correct?</p> <p>24 A. 2123 has my name at the top.</p> <p>25 Q. 2124 has Dr. Chingren's name at the top; is that</p>
<p style="text-align: right;">Page 95</p> <p>1 A. Carol Kruse at the bottom and my handwritten</p> <p>2 note at the top.</p> <p>3 Q. And what was the procedure that's listed on that</p> <p>4 form?</p> <p>5 A. Says, "Procedure, clot filter placement."</p> <p>6 Q. All right. There's a spot on that form that</p> <p>7 says, "I've also been made aware of certain risk and</p> <p>8 consequences associated with this particular</p> <p>9 operation or procedure." What is the reason to have</p> <p>10 that on the form?</p> <p>11 We're going to fix it --</p> <p>12 A. Do you want my honest answer?</p> <p>13 Q. I guess honest is what we're after today.</p> <p>14 A. Because even though this paperwork says you can</p> <p>15 die, which would be the worst outcome, we still</p> <p>16 sometimes write possibilities that are common but</p> <p>17 don't include everything that could be detrimental to</p> <p>18 the patient. And sometimes it's, do this for legal</p> <p>19 implications as well as informing the patient.</p> <p>20 Q. Informed consent for any procedure is important,</p> <p>21 correct?</p> <p>22 A. Uh-huh, yes.</p> <p>23 Q. It's important that the patient be given</p> <p>24 sufficient -- and the physician themselves, have</p> <p>25 sufficient information about a procedure to make an</p>	<p style="text-align: right;">Page 97</p> <p>1 right?</p> <p>2 A. Correct, Dr. Chingren's name at the top and</p> <p>3 usually these are in that physical chart that follows</p> <p>4 the patient.</p> <p>5 Q. All right. Now, on 2124, in the section related</p> <p>6 to certain risks and consequence, there's handwriting</p> <p>7 on 2124; is that correct?</p> <p>8 A. Correct, on 2124, that's my handwriting 'cause</p> <p>9 when I was in training one of the attendings said</p> <p>10 that that was important in a lawsuit that she once</p> <p>11 had and the patient was informed of certain risks.</p> <p>12 And so I, I kind of make it a habit to write a little</p> <p>13 extra sometimes, even though we cover, cover the</p> <p>14 informed consent with the patient.</p> <p>15 Q. All right. The handwriting, your handwriting</p> <p>16 appears on Dr. Chingren's consent related to the</p> <p>17 total knee procedure, why is it there?</p> <p>18 A. I would assume that I accidentally looked in the</p> <p>19 chart and wrote at the bottom of that similar consent</p> <p>20 the most common risk that I would see for her.</p> <p>21 Q. And so when we look at the second page or Bates</p> <p>22 Page 2296 of Exhibit 2124, whose signature appears at</p> <p>23 the bottom of that page?</p> <p>24 A. At the end of 2124 is my signature, dated</p> <p>25 7/8/2009. And Carol's in the middle on the same</p>

<p style="text-align: right;">Page 98</p> <p>1 date.</p> <p>2 MS. HELM: I got it.</p> <p>3 Q. (BY MR. ARBON) So, just so we understand and get</p> <p>4 it clarified, the generic or the general risks of any</p> <p>5 invasive procedure, surgical procedure are identical</p> <p>6 on both Page 21 and 23, that's a form that is used by</p> <p>7 the hospital, correct?</p> <p>8 A. It's a hospital mandated form.</p> <p>9 Q. All right. The specific risks that were warned</p> <p>10 about in relation to clot filter placement actually</p> <p>11 appear on 2124?</p> <p>12 A. The common ones that I thought were common</p> <p>13 listed infection, contrast reaction, hemothorax.</p> <p>14 Q. And those are the risks particular to the IVC</p> <p>15 placement procedures that you were documenting with</p> <p>16 regard to Ms. Kruse's procedure; is that fair?</p> <p>17 A. They were possible complications of her</p> <p>18 procedure.</p> <p>19 Q. Okay. And that's what you were documenting, you</p> <p>20 just wrote them on the wrong page?</p> <p>21 A. That's what it appears, I was trying to document</p> <p>22 well.</p> <p>23 Q. All right. And that was your intent to --</p> <p>24 A. That's my intent.</p> <p>25 Q. -- document well and document the risks that you</p>	<p style="text-align: right;">Page 100</p> <p>1 A. I know it's a possible for filters.</p> <p>2 Q. (BY MR. ARBON) Migration -- or I'm being very</p> <p>3 specific about caudal migration.</p> <p>4 A. I've been trained that they can migrate.</p> <p>5 Q. And I guess that's specifically my point here,</p> <p>6 sir. Because it's important 'cause that's the</p> <p>7 condition we're facing.</p> <p>8 Were you in your training more or less advised</p> <p>9 that filters can migrate, that they can move?</p> <p>10 A. Normally we taught that they tilt. That's the</p> <p>11 one thing that you're taught. But there are other</p> <p>12 complications that can occur, they can break, they</p> <p>13 can move, they can penetrate, other bad things can</p> <p>14 happen.</p> <p>15 Q. Before you experienced this with your patient,</p> <p>16 Carol Kruse in 2011, had you ever seen a caudally</p> <p>17 migrated filter before?</p> <p>18 A. I have not had a patient caudally migrate</p> <p>19 before.</p> <p>20 Q. How many filters do you believe you've placed</p> <p>21 since your fellowship?</p> <p>22 A. Several.</p> <p>23 Q. Can you give me an estimate of how many is</p> <p>24 several?</p> <p>25 A. Between 10 and 20.</p>
<p style="text-align: right;">Page 99</p> <p>1 had --</p> <p>2 A. Correct.</p> <p>3 Q. -- specific to this procedure that you were</p> <p>4 discussing with Ms. Kruse?</p> <p>5 A. That's correct.</p> <p>6 MS. HELM: Object to form.</p> <p>7 Q. (BY MR. ARBON) Did you discuss with Ms. Kruse</p> <p>8 the fact that this filter could migrate to the</p> <p>9 bifurcation of her IVC?</p> <p>10 A. I would -- I discussed several complications,</p> <p>11 but I can't recall at this time the exact words that</p> <p>12 I used. But I usually try and cover a lot of common</p> <p>13 complications.</p> <p>14 Q. Do you know if you discussed migration, specific</p> <p>15 caudal migration with her as a potential?</p> <p>16 A. It's possible.</p> <p>17 Q. Do you recall if I did?</p> <p>18 A. It's -- it's possible.</p> <p>19 Q. All right. So specific caudal migration,</p> <p>20 migration towards the feet?</p> <p>21 A. I'm, it's -- it's unknown, I covered the most</p> <p>22 common ones and those are the ones I documented.</p> <p>23 Q. Would it surprise you if caudal migration is not</p> <p>24 common to all filters?</p> <p>25 MS. HELM: Object to the form.</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. And that's since 2009?</p> <p>2 A. Since 2009.</p> <p>3 Q. And what types of filters have you placed of</p> <p>4 those 10 to 20?</p> <p>5 A. Retrievable and non-retrievable.</p> <p>6 Q. Of retrievable filters, whose brand have you</p> <p>7 placed?</p> <p>8 A. I can't recall.</p> <p>9 Q. You've certainly placed a Bard, at least one?</p> <p>10 A. I've placed a Bard.</p> <p>11 Q. We know about the Bard G2. Do you recall</p> <p>12 replacing any other Bard products -- IVC products in</p> <p>13 your career?</p> <p>14 A. I don't recall the names.</p> <p>15 Q. Do you know if you've ever placed a Denali?</p> <p>16 A. I know the name. It's possible I could have but</p> <p>17 can't say for sure.</p> <p>18 Q. Have you ever placed a, an Eclipse?</p> <p>19 A. I believe I probably have placed an Eclipse.</p> <p>20 Q. How many Bard filters can you recall having</p> <p>21 retrieved in your career?</p> <p>22 A. In private practice, we haven't --</p> <p>23 Q. Yes, sir, let's start there. Private practice.</p> <p>24 A. We haven't had to.</p> <p>25 Q. You attempted a retrieval on Ms. Kruse?</p>

<p style="text-align: right;">Page 102</p> <p>1 A. Correct.</p> <p>2 Q. Have you attempted retrieval of any other --</p> <p>3 retrieval of any other Bard products, IVC products</p> <p>4 that you're aware of, filter?</p> <p>5 A. In fellowship, yes, but in private practice, no.</p> <p>6 Q. In fellowship, do you have an idea of how many</p> <p>7 IVC filters you placed?</p> <p>8 A. No.</p> <p>9 Q. Would it be a similar number, 10 to 20?</p> <p>10 A. That's possible. Less than 50 for sure.</p> <p>11 Q. Okay. When you were placing filters during your</p> <p>12 fellowship, was that with supervision?</p> <p>13 A. Most of the time.</p> <p>14 Q. And when you were placing those filters in</p> <p>15 fellowship, do you recall what filters were being</p> <p>16 used?</p> <p>17 A. Don't recall the names.</p> <p>18 Q. Okay. Do you recall manufacturers? Did you</p> <p>19 place Bard filters?</p> <p>20 A. I don't -- I don't recall.</p> <p>21 Q. Do you recall if you placed Cook filters?</p> <p>22 A. Cook supplied products, so it's always possible.</p> <p>23 Q. Have you ever heard of a Braun?</p> <p>24 A. I've heard the name but don't recall if I placed</p> <p>25 one.</p>	<p style="text-align: right;">Page 104</p> <p>1 their body?</p> <p>2 MS. HELM: Object to form.</p> <p>3 A. I think the patient should have informed</p> <p>4 consent.</p> <p>5 Q. (BY MR. ARBON) And the informed consent they</p> <p>6 read -- they receive is in large part dependant upon</p> <p>7 the adequacy of the information that's been imparted</p> <p>8 to a physician, correct?</p> <p>9 MS. HELM: Object to the form.</p> <p>10 A. The patient does make an informed consent based</p> <p>11 on the information provided.</p> <p>12 Q. (BY MR. ARBON) From the physician?</p> <p>13 A. From the physician and from whatever other</p> <p>14 resource she can get, even the techs.</p> <p>15 Q. Okay. Has Bard ever told you, through sales</p> <p>16 reps or any instructions for use or other</p> <p>17 communications, of a need to develop a protocol to</p> <p>18 track your patients that have G2 filters because of</p> <p>19 the potential for future fracture, perforation,</p> <p>20 migration?</p> <p>21 MS. HELM: Object to the form.</p> <p>22 A. I've not had a Bard rep give me that in writing</p> <p>23 or tell me.</p> <p>24 Q. (BY MR. ARBON) Doctor, if Bard had information</p> <p>25 prior to the implanting of her -- Mrs. Kruse's</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. Have you ever heard of Cordis?</p> <p>2 A. Cordis, I've heard of them as well as a supplier</p> <p>3 for interventional products.</p> <p>4 Q. Have you placed a Cordis TrapEase?</p> <p>5 A. TrapEase, I believe the answer is yes.</p> <p>6 Q. And that's a type of permanent filter?</p> <p>7 A. Correct.</p> <p>8 Q. Was the Cordis TrapEase available to you in</p> <p>9 2009, here at the hospital?</p> <p>10 A. I don't recall.</p> <p>11 Q. Were there any filters other than a G2 available</p> <p>12 to you for use here at the hospital?</p> <p>13 A. Don't recall.</p> <p>14 Q. Back in 2009 when you placed Ms. Kruse's</p> <p>15 filter -- I'm sorry.</p> <p>16 A. All right.</p> <p>17 Q. Did you have the option, if you had decided you</p> <p>18 did not want to use a Bard G2, could you have</p> <p>19 obtained a different filter for her case?</p> <p>20 A. I imagine if I felt that a certain filter needed</p> <p>21 to be placed, I could obtain it if possible. Easier</p> <p>22 said than done.</p> <p>23 Q. Would you agree, sir, that a patient has the</p> <p>24 right to be adequately consented regarding the risks</p> <p>25 and benefits of the device that's going to be put in</p>	<p style="text-align: right;">Page 105</p> <p>1 filter, that the G2 filter had an unacceptable risk</p> <p>2 for caudal migration, is that information that should</p> <p>3 have been provided to you as her physician?</p> <p>4 MS. HELM: Object to the form.</p> <p>5 MR. NOVOTNY: Should have? Are</p> <p>6 you asking him the standard of care questions,</p> <p>7 because doctor's not going to give any standard</p> <p>8 of care opinions.</p> <p>9 MS. HELM: It's objected.</p> <p>10 MR. ARBON: All right, then let's</p> <p>11 put it this way.</p> <p>12 Q. (BY MR. ARBON) If Bard knew that their G2 filter</p> <p>13 presented an unacceptable risk for caudal migration</p> <p>14 and tilt, do you believe Ms. Kruse would have had a</p> <p>15 right to have that information in order to make her</p> <p>16 decision whether to use the filter?</p> <p>17 MS. HELM: Object to the form.</p> <p>18 A. Let's see if I can -- it's a difficult question</p> <p>19 to answer. I'm not sure if I -- if you're asking if</p> <p>20 the product was unsafe, would that impact</p> <p>21 Mrs. Kruse's consent, I would say yes.</p> <p>22 Q. (BY MR. ARBON) And I guess it has to do with the</p> <p>23 product safety, certainly.</p> <p>24 A. Okay.</p> <p>25 Q. The question is: If in Bard's, internally to</p>

<p style="text-align: right;">Page 106</p> <p>1 Bard, they had recognized that the G2 filter was</p> <p>2 presenting an unacceptable risk of caudal migration</p> <p>3 and tilt, is that information that you believe a</p> <p>4 patient should be a party to if they're going to make</p> <p>5 a decision whether or not to use the filter?</p> <p>6 MS. HELM: Object to the form.</p> <p>7 A. If I understand your question right, the patient</p> <p>8 needs as much information as they can to make an</p> <p>9 adequate decision.</p> <p>10 Q. (BY MR. ARBON) And certainly, if Bard had</p> <p>11 information establishing the G2 filter had an</p> <p>12 unacceptable risk for caudal migration or tilt,</p> <p>13 that's information you as a physician needed in order</p> <p>14 to provide the patient with an adequate risk benefit</p> <p>15 analysis; is that true?</p> <p>16 MS. HELM: Object to the form.</p> <p>17 A. The problems with any product would be good for</p> <p>18 the physician to know.</p> <p>19 MR. ARBON: I'll pass the witness.</p> <p>20 MR. NOVOTNY: Her turn.</p> <p>21 CROSS EXAMINATION</p> <p>22 BY MS. HELM:</p> <p>23 Q. My name is Kate Helm and I represent Bard, the</p> <p>24 two Bard companies that Ms. Kruse has filed a lawsuit</p> <p>25 against. And I have a few, probably more than a few</p>	<p style="text-align: right;">Page 108</p> <p>1 have the opportunity to attend that meeting. When</p> <p>2 did it take place?</p> <p>3 MR. ARBON: Objection to form.</p> <p>4 A. I don't recall the exact date, I would assume</p> <p>5 within the past month.</p> <p>6 Q. (BY MS. HELM) Okay. I saw an e-mail -- I knew</p> <p>7 this was going to happen to me. From your lawyer</p> <p>8 dated March 15, 2017 forwarding where you had signed</p> <p>9 the protective order in this case. Was that meeting</p> <p>10 before or after you signed the protective order?</p> <p>11 A. I think it was before.</p> <p>12 Q. Okay. So you actually had a meeting with</p> <p>13 Mr. Arbon and during that meeting he asked you to</p> <p>14 sign the protective order; is that right or did he</p> <p>15 send it to you later?</p> <p>16 A. I think he sent it later.</p> <p>17 Q. Okay.</p> <p>18 A. But, I would have to ask my counsel.</p> <p>19 Q. Okay. And in this meeting that occurred some</p> <p>20 time before March 15, 2017, did he show you any</p> <p>21 documents?</p> <p>22 A. I'm sorry, say that again?</p> <p>23 Q. Sure. In the meeting -- the e-mail --</p> <p>24 A. Okay.</p> <p>25 Q. -- is dated March 15 and your signature on the</p>
<p style="text-align: right;">Page 107</p> <p>1 follow-up questions. I'm going to try to move as</p> <p>2 quickly as possible. And some of mine are just</p> <p>3 literally going to be follow-up and then I have some</p> <p>4 direct questions.</p> <p>5 The documents that you have looked at today,</p> <p>6 that you said were part of the medical record or part</p> <p>7 of the chart, those are documents that are maintained</p> <p>8 in the regular course of business of treating</p> <p>9 patients here at the hospital; is that right?</p> <p>10 A. Correct, by the hospital.</p> <p>11 Q. And you would have access to those for the</p> <p>12 patients you treat?</p> <p>13 A. Correct.</p> <p>14 Q. And we talked about the notes a little bit and</p> <p>15 we're going to go back through 'em. But the notes in</p> <p>16 particular -- everything has date on it?</p> <p>17 A. It appears so.</p> <p>18 Q. Okay. And those records are prepared on the</p> <p>19 date that's reflected on the chart, correct?</p> <p>20 A. Correct.</p> <p>21 Q. Okay. I want to back up. Both you and</p> <p>22 Mr. Arbon have talked about a meeting you had with</p> <p>23 him previously?</p> <p>24 A. Correct.</p> <p>25 Q. And I didn't have -- I wasn't invited and didn't</p>	<p style="text-align: right;">Page 109</p> <p>1 protective order is March 15, the meeting was before</p> <p>2 that?</p> <p>3 A. Correct, I believe so.</p> <p>4 Q. Okay. So in the meeting before March 15, 2017,</p> <p>5 did Mr. Arbon show you any documents?</p> <p>6 A. I believe there was a document of -- a paper</p> <p>7 produced somewhere about risk of filters.</p> <p>8 Q. Okay. A piece of medical literature or a paper</p> <p>9 that someone had written?</p> <p>10 A. He showed -- he didn't give it to me, but it was</p> <p>11 a -- I think it was from a journal, I don't remember</p> <p>12 the name of the journal though.</p> <p>13 Q. Okay.</p> <p>14 A. 'Cause...</p> <p>15 Q. Did he show you any other documents?</p> <p>16 A. Well, we went over the medical record pieces.</p> <p>17 There was -- he didn't give me any documents. There</p> <p>18 was a discussion of an e-mail and that's all I can --</p> <p>19 from Bard.</p> <p>20 Q. And the e-mail that he discussed with you, was</p> <p>21 that the e-mail that eventually got marked as 2110?</p> <p>22 A. I don't recall if that was the exact e-mail.</p> <p>23 Q. And this e-mail that he discussed with you, did</p> <p>24 he -- did he read to you from the e-mail?</p> <p>25 A. I believe he read from some document that he had</p>



<p style="text-align: right;">Page 110</p> <p>1 in his hand.</p> <p>2 Q. Okay.</p> <p>3 A. If my counsel may be able to, he was there,</p> <p>4 so --</p> <p>5 Q. Okay. Maybe he can help.</p> <p>6 MR. NOVOTNY: At this moment, I'm</p> <p>7 not the witness.</p> <p>8 A. Okay.</p> <p>9 Q. (BY MS. HELM) Unfortunately.</p> <p>10 A. That's fine.</p> <p>11 Q. So Mr. Arbon at this meeting before March 15,</p> <p>12 2017 and before you signed the protective order read</p> <p>13 to you from some Bard internal e-mail; is that right?</p> <p>14 MR. ARBON: Objection to form.</p> <p>15 A. I believe we discussed a comment of an e-mail</p> <p>16 made, but it -- but I didn't, I didn't -- I didn't</p> <p>17 get that e-mail to take it home.</p> <p>18 Q. (BY MS. HELM) Okay. And what was the substance</p> <p>19 or what was the topic in the e-mail?</p> <p>20 A. That there was some concern with the Bard</p> <p>21 product.</p> <p>22 Q. Okay. But as far as you know, the document that</p> <p>23 he read from and discussed with you was not the same</p> <p>24 e-mail that we marked as 2110?</p> <p>25 A. I don't -- actually, wouldn't know 'cause, I</p>	<p style="text-align: right;">Page 112</p> <p>1 A. Uh-huh.</p> <p>2 Q. What else did you talk about?</p> <p>3 A. That he was from Texas and went to school in</p> <p>4 Oklahoma and that I looked at his website for his law</p> <p>5 firm.</p> <p>6 Q. Anything else?</p> <p>7 A. No. No.</p> <p>8 Q. Okay. Did you, were you paid for your time for</p> <p>9 that meeting?</p> <p>10 A. No.</p> <p>11 Q. Do you intend to bill them for your time?</p> <p>12 A. No.</p> <p>13 Q. Are you billing for your time today?</p> <p>14 A. Not that I'm aware of, but...</p> <p>15 Q. Okay. Did Mr. Arbon provide you with any</p> <p>16 documents in that meeting, did he --</p> <p>17 A. No, I didn't -- I did not leave the meeting with</p> <p>18 any documents.</p> <p>19 Q. Okay. The copy of the medical record that you</p> <p>20 had with you that day, was it a copy he brought with</p> <p>21 him or did you actually have it?</p> <p>22 A. That, he had. But I think my counsel also had</p> <p>23 the same copies. All of which I think we've</p> <p>24 discussed, except for that one.</p> <p>25 Q. Okay. And we'll get to the July 11, 2011</p>
<p style="text-align: right;">Page 111</p> <p>1 don't think I actually ever received the e-mail in my</p> <p>2 hand to review.</p> <p>3 Q. Okay. Other than the e-mail, did he discuss any</p> <p>4 other documents with you in the meeting before you</p> <p>5 signed the protective order?</p> <p>6 A. I don't believe so. I think it was mainly the</p> <p>7 medical record.</p> <p>8 Q. Did Mr. Arbon ask you if you -- to offer any</p> <p>9 opinions in this case?</p> <p>10 A. If he asked any opinions, my answer would have</p> <p>11 been they would only be opinions based solely on</p> <p>12 Mrs. Kruse, and not an expert witness --</p> <p>13 Q. Okay.</p> <p>14 A. -- type opinion.</p> <p>15 Q. Okay. When this meeting took place, was it just</p> <p>16 the three of you; you --</p> <p>17 A. Correct.</p> <p>18 Q. -- Mr. Arbon and your lawyer? And where did the</p> <p>19 meeting take place?</p> <p>20 A. In this room.</p> <p>21 Q. And how long did it last?</p> <p>22 A. One to two hours.</p> <p>23 Q. Okay. You talked about a Bard e-mail, you</p> <p>24 talked about the medical record, which we're going to</p> <p>25 get to go through again.</p>	<p style="text-align: right;">Page 113</p> <p>1 document.</p> <p>2 Okay, so the only two documents that you --</p> <p>3 outside of your medical record that you specifically</p> <p>4 recall Mr. Arbon discussing with you were a paper on</p> <p>5 the risks of filters and a Bard internal e-mail; is</p> <p>6 that right?</p> <p>7 A. Correct.</p> <p>8 Q. Okay.</p> <p>9 A. Neither one of which I wanted to have a copy of,</p> <p>10 'cause then I would have to read it thoroughly.</p> <p>11 Q. You testified that you had given a deposition</p> <p>12 one time prior?</p> <p>13 A. Correct.</p> <p>14 Q. What were the circumstances of that deposition?</p> <p>15 A. Working in an emergency room and there was a, I</p> <p>16 guess you would say the beginning evaluation, if</p> <p>17 there was any malpractice event.</p> <p>18 Q. Okay. Were you --</p> <p>19 A. It was by telephone.</p> <p>20 Q. It was a telephone deposition. Were you a</p> <p>21 witness in that?</p> <p>22 A. No, I think -- I think they were probably trying</p> <p>23 to see if I did proper standard of care.</p> <p>24 Q. Okay.</p> <p>25 A. Then there was, after that meeting nothing.</p>

<p style="text-align: right;">Page 114</p> <p>1 Nothing ever happened.</p> <p>2 Q. Okay. All right. I just wanted to check that</p> <p>3 box because I had not had a follow-up on that.</p> <p>4 Have you ever served as an expert witness?</p> <p>5 A. No -- or wait a minute, once, maybe once, 2000</p> <p>6 and...</p> <p>7 MR. NOVOTNY: CV?</p> <p>8 A. When I was in Alabama several years ago,</p> <p>9 practicing occupational medicine, there was a work</p> <p>10 comp claim that I had to go to the courthouse and sit</p> <p>11 in the courthouse stand and answer medical questions.</p> <p>12 Q. (BY MS. HELM) Okay.</p> <p>13 A. That's the only time I can recall.</p> <p>14 Q. Okay. So prior to today, there were only --</p> <p>15 there have only been two times where you've had to</p> <p>16 swear to tell the truth in a court or court like</p> <p>17 proceeding?</p> <p>18 A. Yes.</p> <p>19 Q. One was a telephone interview of some kind --</p> <p>20 A. Yes.</p> <p>21 Q. -- relating to treatment in an ER. Is that when</p> <p>22 you were a resident?</p> <p>23 A. No, this was 2000 and -- approximately -- maybe</p> <p>24 1997, 1998 years.</p> <p>25 Q. Okay. And what were you doing in those years?</p>	<p style="text-align: right;">Page 116</p> <p>1 in 2009, you've placed somewhere between 10 or 20 IVC</p> <p>2 filters?</p> <p>3 A. Correct.</p> <p>4 Q. And those are both retrievable and permanent?</p> <p>5 A. Correct.</p> <p>6 Q. Okay. If your fellowship ended late June, early</p> <p>7 July and you implanted Ms. Kruse's filter on</p> <p>8 July 8th, 2009, do you think that was the first</p> <p>9 filter you implanted in private practice?</p> <p>10 A. No, actually, there was -- I'm pretty sure there</p> <p>11 was a filter placed almost a week before.</p> <p>12 Q. Okay. So this was the second one in private</p> <p>13 practice?</p> <p>14 A. Correct.</p> <p>15 Q. Okay.</p> <p>16 A. At a minimum.</p> <p>17 Q. Okay. And is it my -- did I understand your</p> <p>18 testimony that the attempt to retrieve Ms. Kruse's</p> <p>19 filter in 2011 was your first attempt to retrieve a</p> <p>20 filter in private practice?</p> <p>21 A. In private practice.</p> <p>22 Q. Okay.</p> <p>23 A. We had done it in fellowship before, but in</p> <p>24 private practice.</p> <p>25 Q. Okay. And how many do you think you had</p>
<p style="text-align: right;">Page 115</p> <p>1 A. I was the ER staff physician.</p> <p>2 Q. Okay. And where was that?</p> <p>3 A. University of Iowa.</p> <p>4 Q. Okay. And then the second one was when you were</p> <p>5 actually in private practice in Alabama?</p> <p>6 A. Yeah, that would be approximately somewhere</p> <p>7 between the years of 1999 and 2004.</p> <p>8 Q. Okay. And you were working as an</p> <p>9 occupational --</p> <p>10 A. Correct.</p> <p>11 Q. -- medicine? Okay.</p> <p>12 A. Correct.</p> <p>13 Q. And you testified in that case relating to the</p> <p>14 treatment of some patient who had a workers'</p> <p>15 compensation claim?</p> <p>16 A. Carpal tunnel, correct.</p> <p>17 Q. Okay. Let's go back and talk about IVC filters</p> <p>18 and your experience with IVC filters and I think I</p> <p>19 caught this but I want to make sure. While you were</p> <p>20 in fellowship, you placed somewhere less than 50</p> <p>21 filters?</p> <p>22 A. Correct, correct.</p> <p>23 Q. And those are retrievable or permanent, correct?</p> <p>24 A. Correct.</p> <p>25 Q. Okay. And since you went into private practice</p>	<p style="text-align: right;">Page 117</p> <p>1 retrieved in fellowship?</p> <p>2 A. I recall one case for sure because it was tilted</p> <p>3 and -- but that was successful.</p> <p>4 Q. Okay. So you only recall one retrieval attempt</p> <p>5 while you were in fellowship and it was a tilted</p> <p>6 filter and you were able to retrieve it?</p> <p>7 A. Correct.</p> <p>8 Q. Do you know -- okay.</p> <p>9 A. And that was a one-year fellowship.</p> <p>10 Q. Okay. And then since your attempt -- okay, from</p> <p>11 when you went into private practice until April of</p> <p>12 2011, when you attempted to retrieve Ms. Kruse's</p> <p>13 filter, did you not have any filter retrievals,</p> <p>14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. And since Ms. Kruse's retrieval in -- or</p> <p>17 retrieval attempt in April of 2011, you have not</p> <p>18 retrieved any filters; is that right?</p> <p>19 A. Correct.</p> <p>20 Q. Okay. Okay. Do you know what kind of filters</p> <p>21 the hospital's using today?</p> <p>22 A. No.</p> <p>23 Q. Okay. Is it fair to say that you implant the</p> <p>24 filter that is available at the time of the implant?</p> <p>25 A. Yes.</p>

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<p>1 Q. And someone else makes the purchasing decision</p> <p>2 on what type of filters to purchase for the hospital?</p> <p>3 A. Somebody else purchases 'em. I'm sure if I had</p> <p>4 to have something, they would -- there would be a</p> <p>5 process for doing that.</p> <p>6 Q. Is Mary Lanning owned by a --</p> <p>7 A. No.</p> <p>8 Q. Okay.</p> <p>9 A. But there's a consortium with other hospitals.</p> <p>10 Q. Okay. So there's a buying consortium?</p> <p>11 A. Correct.</p> <p>12 Q. And you are not part of the group that makes the</p> <p>13 buying decisions?</p> <p>14 A. Correct.</p> <p>15 Q. Okay. Ms. Kruse was referred to you by</p> <p>16 Dr. Chingren?</p> <p>17 A. Correct.</p> <p>18 Q. And was it your understanding that she was</p> <p>19 having a knee replacement surgery?</p> <p>20 A. Correct.</p> <p>21 Q. Okay. Was it also your understanding that she</p> <p>22 had had a history of both DVT and PE?</p> <p>23 A. Correct, two -- two PEs and a DVT. And based on</p> <p>24 the surgery, difficulty with anti coagulation plans.</p> <p>25 Q. Okay. So it was your understanding that with</p>	<p>1 dictated note relating to the implantation of</p> <p>2 Ms. Kruse's IVC G2 filter on July 8, 2009; is that</p> <p>3 correct?</p> <p>4 A. Let -- and let me interrupt, we'll come back to</p> <p>5 your question. To fill out the indication question</p> <p>6 that you had, there's also an outpatient -- I believe</p> <p>7 a nurse practitioner note talking about the need for</p> <p>8 a filter.</p> <p>9 Q. Okay. Thank you.</p> <p>10 A. So that's in the medical record --</p> <p>11 Q. Okay.</p> <p>12 A. -- as well as...</p> <p>13 Q. Okay. Before --</p> <p>14 A. But anyway, so repeat your question.</p> <p>15 Q. Sure, let's --</p> <p>16 MR. ARBON: Object to the</p> <p>17 responsiveness of the answer.</p> <p>18 Q. (BY MS. HELM) Okay, let's go back and let me ask</p> <p>19 the question: There was an outpatient note that was</p> <p>20 part -- that's part of the record, there was a</p> <p>21 recommendation from Dr. Chingren, both of which</p> <p>22 recommended that Ms. Kruse have a filter implanted</p> <p>23 because of her history of PE and DVT, correct?</p> <p>24 A. Correct.</p> <p>25 Q. And also part -- the recommendation was also</p>
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<p>1 her history of PE and DVT and because of the nature</p> <p>2 of the surgery she had to be taken off of her</p> <p>3 Coumadin or whatever anti coagulant she was on that</p> <p>4 Dr. Chingren recommended that she be -- have an IVC</p> <p>5 filter implanted; is that right?</p> <p>6 A. Correct, it seemed appropriate indications.</p> <p>7 Q. And you agreed with that recommendation?</p> <p>8 A. Yes.</p> <p>9 Q. And then you did an independent evaluation of</p> <p>10 whether she was an appropriate candidate for an IVC</p> <p>11 filter by in part measuring her inferior vena cava?</p> <p>12 A. Correct, with a CT to provide accurate</p> <p>13 information. 'Cause as a physician, you want to --</p> <p>14 it's best if you can tell where the renal arteries</p> <p>15 are and sometimes with vena gram, it can be</p> <p>16 difficult.</p> <p>17 Q. Okay.</p> <p>18 A. My intent was to try and do a good job.</p> <p>19 Q. After you implanted the filter, did you see</p> <p>20 Ms. Kruse again before the retrieval attempt?</p> <p>21 A. No.</p> <p>22 Q. Okay. And I would ask you to look at Exhibit</p> <p>23 2115.</p> <p>24 (Discussion off the record.)</p> <p>25 Q. (BY MS. HELM) And Doctor, Exhibit 2115 is your</p>	<p>1 made because they felt like she needed to go off of</p> <p>2 her anti coagulants because of the nature of the</p> <p>3 surgery, correct?</p> <p>4 A. And there's a documentation in that primary care</p> <p>5 note that she chose not to postpone the surgery to</p> <p>6 pursue other options.</p> <p>7 Q. Okay.</p> <p>8 A. That's somebody else's note.</p> <p>9 Q. Okay. Ms. Kruse was anxious to have the surgery</p> <p>10 done, wasn't she, the knee surgery?</p> <p>11 A. I wouldn't know.</p> <p>12 Q. Okay. Based on the -- recommendation of</p> <p>13 Dr. Chingren and the primary care provider and the</p> <p>14 referral to you, you then from an interventional</p> <p>15 radiologist perspective evaluated her for the IVC</p> <p>16 filter, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And you've already testified about that --</p> <p>19 A. Correct.</p> <p>20 Q. -- correct?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. And your note that you dictated on 2115,</p> <p>23 I have one question about it. And it says,</p> <p>24 "Impression, IVC G2 retrieval filter deployment,"</p> <p>25 it's at the bottom; do you see that?</p>

<p style="text-align: right;">Page 122</p> <p>1 A. IVC G2 filter deployment, correct.</p> <p>2 Q. Well actually, will you read that again?</p> <p>3 A. IVC G2 retrievable filter deployment.</p> <p>4 Q. Okay. So that word that says retrieval, should</p> <p>5 actually say retrievable, correct?</p> <p>6 A. Oh, I didn't even notice, that's correct.</p> <p>7 Q. Okay. So what you implanted in Ms. Kruse was a</p> <p>8 retrievable filter, correct?</p> <p>9 A. It's a filter that can be permanent or</p> <p>10 retrievable. Or retrieved.</p> <p>11 Q. Okay. And it can be retrieved in the manner in</p> <p>12 which you attempted to do it percutaneously, correct?</p> <p>13 A. As my training, yes.</p> <p>14 Q. Okay. And would you explain what percutaneous</p> <p>15 means.</p> <p>16 A. To penetrate the skin.</p> <p>17 Q. Okay. And so it's a procedure where you</p> <p>18 actually do a, like, a needle prick in her neck and</p> <p>19 go in through the vein, you don't have to do an open</p> <p>20 incision?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. But you would agree that you implanted</p> <p>23 and documented that you implanted a retrievable</p> <p>24 filter?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 124</p> <p>1 and because she was suffering from PE and DVT while</p> <p>2 on anti coagulants?</p> <p>3 MR. ARBON: Objection to form.</p> <p>4 A. In my own words, she was an adequate candidate</p> <p>5 for a permanent filter.</p> <p>6 MR. ARBON: Objection,</p> <p>7 responsiveness.</p> <p>8 (Discussion off the record.)</p> <p>9 Q. (BY MS. HELM) Let's talk about your retrieval or</p> <p>10 retrieval attempt. And let me back up. No, let me</p> <p>11 back up first of all.</p> <p>12 You talked about previously about the risks and</p> <p>13 benefits of -- the risks that you explained to</p> <p>14 Ms. Kruse when you implanted the filter; do you</p> <p>15 remember that testimony?</p> <p>16 A. Correct.</p> <p>17 Q. And you also -- Mr. Arbon spent a lot of time</p> <p>18 with you talking to you about the IFU and if you</p> <p>19 would get --</p> <p>20 A. Package insert correct, okay.</p> <p>21 Q. Yes. If you would get that exhibit back in</p> <p>22 front of you?</p> <p>23 MR. NOVOTNY: 2109.</p> <p>24 MS. HELM: Thank you.</p> <p>25 Q. (BY MS. HELM) Dr. Smith, at the time you</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. Okay. Thank you.</p> <p>2 Do you know why between -- do you know if or why</p> <p>3 between July, 2009 when you implanted this</p> <p>4 retrievable filter in Ms. Kruse and 2011 when she</p> <p>5 came back, her filter was not retrieved?</p> <p>6 A. Because it was meant to be a permanent filter.</p> <p>7 She had high risk indications, two pulmonary emboli,</p> <p>8 DVT, anti coagulation issues, social issues -- the</p> <p>9 moving social issues, moving from the Lincoln move.</p> <p>10 And seems she had indication that were appropriate</p> <p>11 and if we didn't place it, we may be meeting for</p> <p>12 other reasons.</p> <p>13 Q. Okay. So it was your --</p> <p>14 MR. ARBON: Objection to the</p> <p>15 responsiveness of the answer.</p> <p>16 Q. (BY MS. HELM) It was your opinion when you</p> <p>17 implanted the filter in Ms. Kruse in July of 2008</p> <p>18 (sic) that she was going to need both the filter and</p> <p>19 long-term anti coagulation; is that fair?</p> <p>20 A. I'm sorry, repeat the question.</p> <p>21 Q. Sure. Was it your opinion based on her history</p> <p>22 that was provided to you that at the time you</p> <p>23 implanted Ms. Kruse's filter in 2009, she needed the</p> <p>24 filter not only for the surgery, but she needed it</p> <p>25 beyond the surgery because of her medical history,</p>	<p style="text-align: right;">Page 125</p> <p>1 implanted Ms. Kruse's filter in July of 2009, you</p> <p>2 were aware that IVC filters could migrate; is that</p> <p>3 right?</p> <p>4 A. I believe it's a possibility I knew that they</p> <p>5 could move from their position.</p> <p>6 Q. Okay. And were you aware that that was a</p> <p>7 complication of all IVC filters?</p> <p>8 A. Definitely not permanent filters.</p> <p>9 Q. Okay.</p> <p>10 A. But I believe it's -- at that time in 2009, the</p> <p>11 literature at that time was probably coming out that</p> <p>12 there were issues with IVC filters.</p> <p>13 Q. Okay. In fact, Bard in the package insert as</p> <p>14 you called it or the IFU, Exhibit 2109, on -- under</p> <p>15 Section G, potential complication; do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Okay.</p> <p>18 A. Page 2.</p> <p>19 Q. And the very first bullet point under potential</p> <p>20 complications is, "Movement or migration of the</p> <p>21 filter is a known complication of vena cava filters."</p> <p>22 A. That's what it says, correct.</p> <p>23 Q. Okay. So in 2009, when you implanted</p> <p>24 Ms. Kruse's filter, Bard told you in the package</p> <p>25 insert that migration was a known complication of the</p>

<p style="text-align: right;">Page 126</p> <p>1 filters; is that right?</p> <p>2 A. It's in the package insert that would come with</p> <p>3 the box.</p> <p>4 Q. Okay. If you go up further on -- and my</p> <p>5 packaging insert may be different than yours, it's</p> <p>6 above F, there's a -- above the precautions, there's</p> <p>7 a note under reference, potential complication</p> <p>8 sections for other -- "Further information regarding</p> <p>9 other known filter complications."</p> <p>10 And do you see that note under No. 1?</p> <p>11 A. Not yet. Can you be more specific?</p> <p>12 Q. Okay.</p> <p>13 A. On --</p> <p>14 Q. We'll skip it. And let's move on, because --</p> <p>15 okay, let me get my copy of 2109 because I think it</p> <p>16 will -- I'm working off of one that's printed</p> <p>17 different.</p> <p>18 MR. NOVOTNY: Here's mine.</p> <p>19 Q. (BY MS. HELM) Yeah, but I'm going to move on and</p> <p>20 ask you to look at Page 4. It says, No. 4 at the</p> <p>21 bottom of Exhibit 2109.</p> <p>22 A. Yes.</p> <p>23 Q. And you see the bar chart?</p> <p>24 A. Yes.</p> <p>25 Q. And immediately below the bar chart it says, "Of</p>	<p style="text-align: right;">Page 128</p> <p>1 caudal migration."</p> <p>2 A. Yes.</p> <p>3 Q. "Fracture, PE, filter tilt, penetration, caval</p> <p>4 occlusion, non-occlusive caval thrombosis and caval</p> <p>5 stenosis at implant site post successful retrieval."</p> <p>6 Did I read that correctly?</p> <p>7 A. Correct.</p> <p>8 Q. Okay. So again, in this IFU, which we've marked</p> <p>9 as 2109, Bard identified that caudal migration was a</p> <p>10 potential complication of the G2 filter; did it not?</p> <p>11 MR. ARBON: Objection to form.</p> <p>12 A. It does say caudal migration on the package</p> <p>13 insert.</p> <p>14 Q. (BY MS. HELM) Okay. And if you would look at</p> <p>15 the very last page, it has very little print on it.</p> <p>16 A. Yes.</p> <p>17 Q. You see that at the bottom where it says</p> <p>18 PK510090RED.0 and then it has the date 03/09?</p> <p>19 A. Yes, I see that.</p> <p>20 Q. So if this version of the IFU is dated March of</p> <p>21 '09, that was before you implanted Ms. Kruse's filter</p> <p>22 in July of '09; is that right?</p> <p>23 A. That date precedes the filter placement.</p> <p>24 Q. Okay. Thank you.</p> <p>25 Okay, do you know -- do you personally know if</p>
<p style="text-align: right;">Page 127</p> <p>1 61 filter retrievals, three technical failures for</p> <p>2 retrieval resulted from inability to engage the</p> <p>3 filter apex with the Recovery Cone Removal System due</p> <p>4 to filter tilt leading to embedding of the filter</p> <p>5 apex in the vena cava wall."</p> <p>6 Did I read that correctly?</p> <p>7 A. That's correct, so the filter can tilt and you</p> <p>8 can't engage it.</p> <p>9 Q. And in the package insert that came with</p> <p>10 Ms. Kruse's G2 filter, Bard told you that tilt was a</p> <p>11 possible complication and inability to retrieve with</p> <p>12 the cone because of tilt was a possible complication,</p> <p>13 correct?</p> <p>14 A. If this is --</p> <p>15 MR. ARBON: Objection to form.</p> <p>16 A. If this package insert was in the box that I</p> <p>17 opened, it does state that there are complications to</p> <p>18 the filter.</p> <p>19 Q. (BY MS. HELM) Including tilt and the inability</p> <p>20 to retrieve?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. And below that, you see the sentence that</p> <p>23 starts asymptomatic?</p> <p>24 A. Yes.</p> <p>25 Q. It says, "Asymptomatic complications included</p>	<p style="text-align: right;">Page 129</p> <p>1 Ms. Kruse was having any physical symptoms as it</p> <p>2 related to her filter or were those simply relayed to</p> <p>3 you from some other source?</p> <p>4 A. The -- I would have discovered that when she</p> <p>5 presented for the filter retrieval and read the note</p> <p>6 that preceded that.</p> <p>7 Q. Okay.</p> <p>8 A. And it talked about a pulling sensation in her</p> <p>9 lower abdomen.</p> <p>10 Q. Okay. I want to talk to you about -- before we</p> <p>11 talk about the retrieval, I want to talk to you about</p> <p>12 your testimony that there was a Bard representative</p> <p>13 in the room when you attempted to retrieve --</p> <p>14 A. Correct, it was a male representative.</p> <p>15 Q. Okay. If you would like at Exhibit 21 -- it's</p> <p>16 the retrieval note.</p> <p>17 MR. NOVOTNY: 18.</p> <p>18 Q. (BY MS. HELM) You mentioned previously...</p> <p>19 (Discussion off the record.)</p> <p>20 Q. You testified previously about the need to</p> <p>21 document. Does anywhere on 2118 mention that there</p> <p>22 was a Bard representative present when you attempted</p> <p>23 to retrieve Ms. Kruse's filter?</p> <p>24 A. My note does not have a Bard representative name</p> <p>25 on it.</p>



<p style="text-align: right;">Page 130</p> <p>1 Q. Okay. What is a -- and would you also look at</p> <p>2 Exhibit 2121?</p> <p>3 A. Yes.</p> <p>4 Q. And those are your handwritten notes?</p> <p>5 A. Yes.</p> <p>6 Q. Both before and after the procedure; is that</p> <p>7 right?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And nowhere in those notes do you</p> <p>10 indicate that there was a Bard representative or a</p> <p>11 non-employee of the hospital present during the</p> <p>12 procedure; do you?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. Do you know what a diagnostic imaging</p> <p>15 timeout is?</p> <p>16 A. I'm familiar with the name.</p> <p>17 Q. Okay. And what is that?</p> <p>18 A. That is a recently implemented procedure that</p> <p>19 varies per hospital that talks about questions that</p> <p>20 can help patient safety.</p> <p>21 Q. Okay. And it's a checklist that documents to</p> <p>22 make sure everything's being done right before you</p> <p>23 proceed with the procedure; is that right?</p> <p>24 A. Tries to confirm most of the common problems</p> <p>25 that can happen.</p>	<p style="text-align: right;">Page 132</p> <p>1 retrieval date, okay.</p> <p>2 Q. Okay. So this is the date that you retrieved,</p> <p>3 attempted to retrieve Ms. Kruse's filter; is that</p> <p>4 right?</p> <p>5 A. That's correct.</p> <p>6 Q. And this document is part of Ms. Kruse's chart,</p> <p>7 it has her name at the bottom, right?</p> <p>8 A. Correct.</p> <p>9 Q. And it has her patient number 0257272, correct?</p> <p>10 A. Correct. And this is filled out by the</p> <p>11 technologist usually.</p> <p>12 Q. Okay. And this is -- and on this chart it says,</p> <p>13 "Documentation of members present during timeout."</p> <p>14 Do you see that?</p> <p>15 A. Yes, I see that.</p> <p>16 Q. Okay. And it indicates that you were there as</p> <p>17 the radiologist; is that right?</p> <p>18 A. That's correct.</p> <p>19 Q. It indicates that Joyce Breck (sic) and Michelle</p> <p>20 White were there as technologist; is that right?</p> <p>21 A. Yes, Bieck, it might be spelled B-I-E-C-K.</p> <p>22 Q. Thank you. It indicates that there were two</p> <p>23 ultrasound technologist, Megan Ross and April</p> <p>24 Eikmeier; is that right?</p> <p>25 A. That's correct, E-I-K-M-E-I-E-R.</p>
<p style="text-align: right;">Page 131</p> <p>1 Q. Okay. I'm going to show you what I've marked as</p> <p>2 Exhibit 2125. I don't have an extra copy. It's</p> <p>3 Bates number 34, sorry. It's Bates number 34.</p> <p>4 MR. ARBON: Is it Mary Lanning?</p> <p>5 MS. HELM: That's it.</p> <p>6 MR. NOVOTNY: I can show him my</p> <p>7 copy, you want to keep your copy?</p> <p>8 MR. ARBON: Give us a chance to</p> <p>9 look at it or if I can just look at it and pass</p> <p>10 it right back to you.</p> <p>11 A. Yeah, I'm trying to figure out the date.</p> <p>12 MR. MACDONALD: Here you go.</p> <p>13 MR. ARBON: Nevermind. Thank you.</p> <p>14 Q. (BY MS. HELM) Dr. Smith, you've been handed what</p> <p>15 is going to be marked as Exhibit 2125. And that is a</p> <p>16 diagnostic imaging timeout form for Mary Lanning</p> <p>17 memorial health care; is that right?</p> <p>18 (Exhibit No. 2125, marked for identification.)</p> <p>19 A. It appears that's correct.</p> <p>20 Q. And --</p> <p>21 A. And the date is --</p> <p>22 Q. If you look at the top --</p> <p>23 A. -- 4/7/2011.</p> <p>24 Q. Okay. And the patient is --</p> <p>25 A. So that would be the re -- that would be the</p>	<p style="text-align: right;">Page 133</p> <p>1 Q. And that there was a nurse in the room, Regina</p> <p>2 Anderson; is that right?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. This document does not indicate that</p> <p>5 there was any other person in the room; is that</p> <p>6 right?</p> <p>7 A. That's correct.</p> <p>8 Q. Okay. Is there anything in the medical record</p> <p>9 that indicates that there was a Bard representative</p> <p>10 in the room?</p> <p>11 A. I don't believe so.</p> <p>12 Q. And you would agree with me, that that is</p> <p>13 something that should be documented, would you not?</p> <p>14 A. It would be best to document the appropriate</p> <p>15 people in the room. So it looks like the RT tech</p> <p>16 wrote who she had down.</p> <p>17 Q. But she did not include a Bard representative?</p> <p>18 A. That's, it appears that way.</p> <p>19 Q. Okay. And you didn't include it in your</p> <p>20 progress note or in your dictated note?</p> <p>21 A. I don't normally do that in my note, that's the</p> <p>22 hospital procedure.</p> <p>23 Q. Okay. After you were unable to retrieve</p> <p>24 Ms. Kruse's filter, did you ever call Bard and tell</p> <p>25 them that you had a complication?</p>

<p style="text-align: right;">Page 134</p> <p>1 A. No, I did not.</p> <p>2 Q. Did you ask the sales rep to call Bard?</p> <p>3 A. No.</p> <p>4 Q. Okay. Did you prepare any type of adverse event</p> <p>5 or incident report for the hospital?</p> <p>6 A. No.</p> <p>7 MR. NOVOTNY: Whoa, we're not</p> <p>8 going to talk about any types of reports you</p> <p>9 gave to the hospital. Under Nebraska law.</p> <p>10 MS. HELM: Okay.</p> <p>11 Q. (BY MS. HELM) So we don't have anything anywhere</p> <p>12 in any of the medical records to indicate that there</p> <p>13 was a Bard representative in the room or who was</p> <p>14 there; is that right?</p> <p>15 A. Not from what you've shown me.</p> <p>16 Q. Okay. Well, you've had an opportunity to look</p> <p>17 at the record. Have you seen it anywhere --</p> <p>18 A. No.</p> <p>19 Q. -- in the record? Okay.</p> <p>20 I want to stay on the retrieval. And you</p> <p>21 testified that, that the Bard representative, you</p> <p>22 told him you weren't able to retrieve the filter; is</p> <p>23 that right?</p> <p>24 A. The Bard representative saw that I was unable to</p> <p>25 retrieve the filter, correct.</p>	<p style="text-align: right;">Page 136</p> <p>1 you -- there was an offer to refer her to go to Grand</p> <p>2 Island where there were two interventional</p> <p>3 radiologist; is that right?</p> <p>4 MR. ARBON: Objection to form.</p> <p>5 A. And refer to Grand Island or Lincoln, whatever</p> <p>6 would facilitate her care.</p> <p>7 Q. Okay. And your referring was to an</p> <p>8 interventional radiologist, correct?</p> <p>9 A. They would be the ones most knowledgeable about</p> <p>10 the procedure.</p> <p>11 Q. Okay. And interventional radiologists don't do</p> <p>12 open procedures like open heart surgery or anything</p> <p>13 like that, do they?</p> <p>14 MR. ARBON: Objection, form.</p> <p>15 A. I would say in general they're not --</p> <p>16 interventional radiologists are not trained to do</p> <p>17 cardiac procedures openly.</p> <p>18 Q. (BY MS. HELM) So your referring was for her to</p> <p>19 be evaluated by another interventional radiologist</p> <p>20 and potentially another percutaneous procedure,</p> <p>21 correct?</p> <p>22 MR. ARBON: Objection to form.</p> <p>23 A. That was the plan.</p> <p>24 Q. (BY MS. HELM) And according to the progress</p> <p>25 note, which is Exhibit 2120, if you need it back,</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. Okay. And you had a conversation with him about</p> <p>2 another procedure that you were aware of?</p> <p>3 A. Correct.</p> <p>4 Q. But that you then decided not to do it; is that</p> <p>5 right?</p> <p>6 A. That's correct.</p> <p>7 Q. Okay. And that procedure, I believe you</p> <p>8 testified, was using a wire to try to move the</p> <p>9 filter; is that right?</p> <p>10 A. That's essentially correct.</p> <p>11 Q. Okay. Had you ever performed that procedure</p> <p>12 before?</p> <p>13 A. No.</p> <p>14 Q. Is part of the reason you chose not to do it</p> <p>15 because you had never done it before?</p> <p>16 A. That would be one reason, but also the duration</p> <p>17 of the procedure, the facilities and then -- and so</p> <p>18 it was chosen not to do that.</p> <p>19 Q. So you made a medical decision not to attempt to</p> <p>20 do it based on your experience, the facilities and</p> <p>21 the equipment you had available to you. And you made</p> <p>22 a medical decision to refer Ms. Kruse to another</p> <p>23 interventional radiologist; is that right?</p> <p>24 A. Right, that's correct.</p> <p>25 Q. Okay. And your record is clear that you --</p>	<p style="text-align: right;">Page 137</p> <p>1 Ms. Kruse indicated that she would contact a doctor</p> <p>2 in Lincoln after she moved to schedule an appointment</p> <p>3 to remove the filter; is that right?</p> <p>4 A. Sorry, repeat the...</p> <p>5 Q. Sure. Ms. Kruse indicated to miss -- is it --</p> <p>6 A. Joyce Bieck.</p> <p>7 Q. Bieck, that she would contact her doctor in</p> <p>8 Lincoln after she has moved to schedule an</p> <p>9 appointment to remove the IVC filter; is that right?</p> <p>10 A. Would not know their -- that's her</p> <p>11 documentation.</p> <p>12 Q. Okay.</p> <p>13 A. So I wouldn't know exact words.</p> <p>14 Q. Okay. But your words were, "Patient will</p> <p>15 follow-up with other care. Complications of IVC</p> <p>16 filters were discussed"; is that right?</p> <p>17 A. Correct.</p> <p>18 Q. And what complications do you -- would you have</p> <p>19 discussed with Ms. Kruse before discharging her?</p> <p>20 A. Complications of a retained filter. And</p> <p>21 commonly those would include, it's already migrated</p> <p>22 so migration doesn't need to be discussed. And that</p> <p>23 they can fracture and the limbs can break on trying</p> <p>24 to retrieve, other complications can occur from</p> <p>25 trying to retrieve a filter.</p>

<p style="text-align: right;">Page 138</p> <p>1 Q. Okay.</p> <p>2 A. And those were discussed on the preoperative</p> <p>3 note as well.</p> <p>4 MR. NOVOTNY: Doctor, are we okay</p> <p>5 in the room to a certain time only?</p> <p>6 THE WITNESS: No, I think, no.</p> <p>7 MR. NOVOTNY: No, okay.</p> <p>8 THE WITNESS: I imagine we have it</p> <p>9 all night.</p> <p>10 MR. NOVOTNY: No, say 'till 5</p> <p>11 o'clock.</p> <p>12 Q. (BY MS. HELM) And Dr. Smith, at some point</p> <p>13 after -- let me back up, were you aware that</p> <p>14 Ms. Kruse is a nurse?</p> <p>15 A. No.</p> <p>16 Q. Okay. At some point after she was discharged in</p> <p>17 April of 2011, either you asked your radiology tech</p> <p>18 or she took it upon herself to follow-up with</p> <p>19 Ms. Kruse; is that right?</p> <p>20 A. It appears she wrote a note.</p> <p>21 Q. That's exhibit --</p> <p>22 A. I don't know the details.</p> <p>23 Q. 2122. And I want to -- if you would put --</p> <p>24 you've got 2120 in front of you. I think you have it</p> <p>25 right there.</p>	<p style="text-align: right;">Page 140</p> <p>1 A. Correct.</p> <p>2 Q. And it says med record No. 0257272.</p> <p>3 A. Correct.</p> <p>4 Q. And that's the same number that's on 2121 and</p> <p>5 2122; is that right?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. So we have some sort of identifying</p> <p>8 number for Ms. Kruse within the hospital within the</p> <p>9 medical record, correct?</p> <p>10 MR. ARBON: Objection, form.</p> <p>11 A. Correct.</p> <p>12 Q. (BY MS. HELM) Okay. So on July 11, 2000 -- I'm</p> <p>13 sorry, July 7, 2011, and I'm going to say her name,</p> <p>14 Breet (sic)?</p> <p>15 A. Bieck.</p> <p>16 Q. Bieck, Ms. Bieck recorded a telephone</p> <p>17 conversation she had with Ms. Kruse and then you</p> <p>18 signed the note as well; is that right?</p> <p>19 MR. ARBON: Objection, form.</p> <p>20 A. Which date?</p> <p>21 MR. NOVOTNY: Indicating.</p> <p>22 A. 7/7/2011. I imagine I would have told her to</p> <p>23 document whatever she talked about so it would be</p> <p>24 clear in the record. And then it does appear I</p> <p>25 signed the bottom to show that I had been involved</p>
<p style="text-align: right;">Page 139</p> <p>1 A. Yes.</p> <p>2 Q. Okay. At the top of Exhibit 2122, it says</p> <p>3 Kruse, Carol D; do you see that? The very top</p> <p>4 there's a line --</p> <p>5 A. Yes, I see her name at the top.</p> <p>6 Q. And then it says, "ID 0257272."</p> <p>7 A. I see those numbers.</p> <p>8 Q. Okay. And these are the same numbers that are</p> <p>9 on the bottom of Exhibit 2120 below Ms. Kruse's name;</p> <p>10 is that right?</p> <p>11 A. They are the same numbers next to her name.</p> <p>12 Q. Okay. And do you have an understanding of</p> <p>13 whether that's -- whether that's a patient number or</p> <p>14 an ID number that tracks her?</p> <p>15 A. I do not.</p> <p>16 Q. Okay. I'm not going to ask you to go through</p> <p>17 all of your records, but I'm going to do one more and</p> <p>18 ask you to look at Exhibit 2115. Sorry, I picked the</p> <p>19 wrong one.</p> <p>20 And on -- this is your note from, actually the</p> <p>21 implantation of Ms. Kruse; is that right?</p> <p>22 A. Yes, 7/8/2009.</p> <p>23 Q. And at the top below the logo and the address of</p> <p>24 the hospital it says, patient name, Carol Kruse,</p> <p>25 Kruse, comma, Carol; do you see that?</p>	<p style="text-align: right;">Page 141</p> <p>1 with that process. And then I made -- I would have</p> <p>2 made the comment that Joyce needs to write down the</p> <p>3 additional part at the bottom, not to delay removal.</p> <p>4 Q. Okay. And according to what Joyce recorded and</p> <p>5 you signed off on, Ms. Kruse said that she would, she</p> <p>6 was going to schedule to have it removed in Lincoln.</p> <p>7 She stated she would call Joyce when she moves to</p> <p>8 Lincoln and will schedule to see Dr. John May --</p> <p>9 Maijins (sic)?</p> <p>10 A. Those...</p> <p>11 Q. On 2122, the handwritten note.</p> <p>12 A. It does say John Majerus and I'm not sure who</p> <p>13 that is. But that would be the conversation that</p> <p>14 Joyce would have had with the patient and I don't</p> <p>15 know the details.</p> <p>16 Q. Okay.</p> <p>17 MR. ARBON: Objection.</p> <p>18 MR. NOVOTNY: M-A-J-A-R-I-S.</p> <p>19 Q. (BY MS. HELM) Do you know --</p> <p>20 MR. ARBON: Objection to</p> <p>21 responsiveness.</p> <p>22 Q. (BY MS. HELM) Do you know if Ms. Bieck has ever</p> <p>23 heard back from Ms. Kruse since July 7, 2011?</p> <p>24 A. I don't know.</p> <p>25 Q. Prior to being contacted for your deposition in</p>

<p style="text-align: right;">Page 142</p> <p>1 this case, did you know that Ms. Kruse had not had</p> <p>2 any further evaluation or treatment relating to her</p> <p>3 IVC filter?</p> <p>4 A. No, I assumed -- I assumed she went to the</p> <p>5 referral recommended.</p> <p>6 MR. ARBON: Objection,</p> <p>7 responsiveness.</p> <p>8 Q. (BY MS. HELM) Thank you.</p> <p>9 I'm not going through this whole thing, I</p> <p>10 promise.</p> <p>11 A. Do what you got to do.</p> <p>12 Q. They send us with -- they send you with a lot</p> <p>13 more than you need, right, Tom?</p> <p>14 MR. MACDONALD: I will say yes.</p> <p>15 Q. (BY MS. HELM) Okay. Dr. Smith, during the</p> <p>16 course of this deposition you were asked about some</p> <p>17 internal documents from Bard; is that right?</p> <p>18 A. Today, yes.</p> <p>19 Q. Okay. And prior to today, have you ever been</p> <p>20 shown internal documents from any product</p> <p>21 manufacturer?</p> <p>22 A. Not that's been presented to date that I'm aware</p> <p>23 of.</p> <p>24 Q. Prior to today, has anybody ever shown you an</p> <p>25 internal e-mail from a product manufacturer?</p>	<p style="text-align: right;">Page 144</p> <p>1 A. I've never seen a company's personal</p> <p>2 communication before.</p> <p>3 Q. And you don't know, as you sit here today,</p> <p>4 whether the information in these documents is</p> <p>5 accurate or correct, do you?</p> <p>6 A. Correct, I -- these are not my documents.</p> <p>7 Q. Okay. And you don't know the context of the</p> <p>8 documents for why they were created or the context in</p> <p>9 which they were used, correct?</p> <p>10 A. Correct.</p> <p>11 Q. Okay. And in fact, they could be drafts,</p> <p>12 couldn't they? In fact, if you look at 2113, it says</p> <p>13 it's a draft, doesn't it, right on the front of it?</p> <p>14 A. The word draft is on the front of Exhibit 2113.</p> <p>15 Q. Okay. And you don't know if the final document</p> <p>16 is the same as the document you were shown today, do</p> <p>17 you?</p> <p>18 A. I don't know anything about personal</p> <p>19 communications in the company.</p> <p>20 Q. Are you aware that Bard has produced over</p> <p>21 8 million pages of documents in this litigation?</p> <p>22 MR. ARBON: Objection, form.</p> <p>23 A. I imagine it's a lot based on television</p> <p>24 commercials.</p> <p>25 MR. ARBON: Objection,</p>
<p style="text-align: right;">Page 143</p> <p>1 A. I don't think I've ever actually seen an e-mail</p> <p>2 with my own eyes.</p> <p>3 Q. Well, the one that you were shown today is 20 --</p> <p>4 A. Yeah, that was read, a small portion. If this</p> <p>5 is the same e-mail that happened a month ago, I don't</p> <p>6 know 'cause I never saw it. But it was a small</p> <p>7 portion of an e-mail read from somebody and I don't</p> <p>8 know if it's the same e-mail.</p> <p>9 MR. ARBON: Objection,</p> <p>10 responsiveness.</p> <p>11 Q. (BY MS. HELM) Okay. Before 2110 was handed to</p> <p>12 you today --</p> <p>13 A. Uh-huh.</p> <p>14 Q. -- have you ever been handed any internal</p> <p>15 documents from any product manufacturer for products</p> <p>16 that you use?</p> <p>17 A. No.</p> <p>18 Q. Okay. And then you were also handed Exhibit</p> <p>19 2111, 2112 and 2113, all of which were represented to</p> <p>20 you to be internal documents from Bard?</p> <p>21 A. Yes, this is the first time that I've seen these</p> <p>22 today.</p> <p>23 Q. Okay. Prior to today, have you ever been</p> <p>24 provided any product manufacturer's internal</p> <p>25 documents related to products that you implant?</p>	<p style="text-align: right;">Page 145</p> <p>1 responsiveness.</p> <p>2 Q. (BY MS. HELM) Have you seen commercials on</p> <p>3 television placed by plaintiff's attorneys</p> <p>4 advertising about IVC filters?</p> <p>5 MR. ARBON: Objection to form.</p> <p>6 A. I have.</p> <p>7 Q. (BY MS. HELM) Do you have a filter? If you have</p> <p>8 a filter, you might be entitled to compensation.</p> <p>9 Call this number. Have you seen those kind of adds?</p> <p>10 A. I think I have.</p> <p>11 MR. ARBON: Objection to form.</p> <p>12 Q. (BY MS. HELM) Okay. Are you aware that dozens</p> <p>13 of Bard witnesses have had their depositions taken</p> <p>14 about Bard's documents and actions they took relating</p> <p>15 to their IVC filters?</p> <p>16 A. I don't know what's happened outside this room.</p> <p>17 Q. Okay. Plaintiff's counsel didn't show you any</p> <p>18 of that testimony today, did he?</p> <p>19 A. I didn't -- I haven't seen anything other than</p> <p>20 what's presented so far.</p> <p>21 Q. Okay. And when it comes to making decisions for</p> <p>22 your patients and weighing the risks and benefits of</p> <p>23 medical devices that you use with your patients, you</p> <p>24 rely on a number of sources, don't you?</p> <p>25 A. Yes.</p>

<p style="text-align: right;">Page 146</p> <p>1 Q. You rely on your training and experience?</p> <p>2 MR. ARBON: Objection, form.</p> <p>3 A. Yes.</p> <p>4 Q. (BY MS. HELM) You rely on your colleague's</p> <p>5 experiences with certain products?</p> <p>6 MR. ARBON: Objection, form.</p> <p>7 A. Yes.</p> <p>8 Q. (BY MS. HELM) You rely on available medical</p> <p>9 literature; is that right?</p> <p>10 MR. ARBON: Objection, form.</p> <p>11 A. I rely my decision based on multiple sources and</p> <p>12 journal articles is one.</p> <p>13 Q. (BY MS. HELM) Okay. And you're not interested</p> <p>14 in getting unreliable information or data?</p> <p>15 A. Not usually.</p> <p>16 Q. Okay. Because getting unreliable information or</p> <p>17 data could adversely impact your risk benefit</p> <p>18 analysis; is that right?</p> <p>19 A. Good data is the best data.</p> <p>20 Q. And in making your treatment decisions for your</p> <p>21 patients, you don't rely on internal information from</p> <p>22 internal documents of manufacturers of medical</p> <p>23 devices, do you?</p> <p>24 MR. ARBON: Objection, form.</p> <p>25 A. That's not a common process.</p>	<p style="text-align: right;">Page 148</p> <p>1 do whatever is appropriate --</p> <p>2 Q. (BY MS. HELM) Okay.</p> <p>3 A. -- to figure out effectiveness and safety</p> <p>4 (sic).</p> <p>5 Q. Are you familiar with what is called the 510K</p> <p>6 process for clearance of a product?</p> <p>7 A. Not, not well.</p> <p>8 Q. Okay. But are you familiar that there's a</p> <p>9 process where a product such as a Bard filter is</p> <p>10 cleared for use without going through randomized</p> <p>11 clinical studies.</p> <p>12 A. I wouldn't know that.</p> <p>13 Q. Okay. Do you rely on information from the FDA</p> <p>14 in making a risk benefit analysis to -- regarding</p> <p>15 products you're going to use with your patients?</p> <p>16 A. Well --</p> <p>17 MR. ARBON: Objection, form.</p> <p>18 A. -- if medication has a black box FDA warning,</p> <p>19 that would affect my treatment and I'm assuming for</p> <p>20 other products as well.</p> <p>21 Q. (BY MS. HELM) Okay. Is it fair to say that</p> <p>22 those first four exhibits that came from Bard were</p> <p>23 represented to you as Bard documents, you can't</p> <p>24 comment as to whether -- how those impacted or would</p> <p>25 have impacted your decision to use the G2 filter in</p>
<p style="text-align: right;">Page 147</p> <p>1 Q. (BY MS. HELM) Okay. Have you ever seen any peer</p> <p>2 reviewed medical literature saying that the G2 filter</p> <p>3 has complication rates that are higher than other</p> <p>4 filters?</p> <p>5 A. I don't recall an article like that.</p> <p>6 Q. Okay. You also asked (sic) a lot of questions</p> <p>7 about, did you know that there was not a clinical</p> <p>8 trial, did you know that the FDA did not approve this</p> <p>9 filter; do you recall those questions?</p> <p>10 A. Vaguely.</p> <p>11 Q. Okay. Are you familiar with the regulatory</p> <p>12 process that a product such as an IVC filter has to</p> <p>13 go through before it can go on the market?</p> <p>14 A. Not probably in detail that everybody -- some</p> <p>15 other people might know.</p> <p>16 Q. Okay. And I assume you would rely on the FDA</p> <p>17 to -- to implement the requirements before it allows</p> <p>18 a product to go on the market?</p> <p>19 A. If that's the process.</p> <p>20 Q. Okay. And FDA did not require a clinical -- a</p> <p>21 level one clinical study for a filter, would you</p> <p>22 question the FDA's decision?</p> <p>23 MR. ARBON: Objection, form.</p> <p>24 A. I assume a level one is, means a randomized</p> <p>25 control trial and I would -- I would think they would</p>	<p style="text-align: right;">Page 149</p> <p>1 Ms. Kruse?</p> <p>2 MR. ARBON: Objection, form.</p> <p>3 A. Those are the first time I seen the documents.</p> <p>4 I wouldn't want to say how they would influence me</p> <p>5 without knowing what they say in detail.</p> <p>6 Q. (BY MS. HELM) And the context in which they were</p> <p>7 created?</p> <p>8 A. I'm sure my opinion would need to be based on a</p> <p>9 lot of things.</p> <p>10 Q. Okay. Fair.</p> <p>11 A. Sorry for being vague on that.</p> <p>12 Q. No, that's quite all right. It's quite all</p> <p>13 right.</p> <p>14 You would expect companies such as Bard to</p> <p>15 continue to assess their products by looking at</p> <p>16 complications and how the product's performing once</p> <p>17 it's in the market; would you not?</p> <p>18 MR. ARBON: Objection, form.</p> <p>19 A. I would assume there's some post market process.</p> <p>20 Q. (BY MS. HELM) Okay. And would you also assume</p> <p>21 that Bard would undertake some sort of a formal</p> <p>22 process to evaluate those complications or events</p> <p>23 that occur once it's in the market?</p> <p>24 MR. ARBON: Objection, form.</p> <p>25 A. I wouldn't know what Bard would do in the normal</p>



<p style="text-align: right;">Page 150</p> <p>1 course of business.</p> <p>2 Q. (BY MS. HELM) Fair. Fair.</p> <p>3 But if Bard updates its package insert, or IFU</p> <p>4 as we call them, to make you aware of the</p> <p>5 complications, it's -- it has experienced or been</p> <p>6 told about, that's information available to you to</p> <p>7 make your risk benefit analysis, correct?</p> <p>8 A. I would expect the package insert to have the</p> <p>9 important information.</p> <p>10 Q. And in 2009, there would also have been medical</p> <p>11 literature available for you to consider in making a</p> <p>12 risk benefit analysis using IVC filters; would you</p> <p>13 agree?</p> <p>14 MR. ARBON: Objection to form.</p> <p>15 A. Can you clarify and reask that question?</p> <p>16 Q. (BY MS. HELM) Sure. In addition to the package</p> <p>17 insert when you make a decision as to whether to use</p> <p>18 a product with a patient, there's often medical</p> <p>19 literature available that you can refer to regarding</p> <p>20 that product, correct?</p> <p>21 MR. ARBON: Objection to form.</p> <p>22 A. I'm sure for all procedures there's background</p> <p>23 medical information.</p> <p>24 Q. (BY MS. HELM) Okay. And in fact, in 2009, there</p> <p>25 was medical literature relating to IVC filters,</p>	<p style="text-align: right;">Page 152</p> <p>1 Q. (BY MS. HELM) Is that right?</p> <p>2 A. Let's see, migration is written down.</p> <p>3 Q. Okay. And if you look again on Page 4 under the</p> <p>4 bar chart, under the clinical experience -- it says</p> <p>5 clinical experience at the top of the page and then</p> <p>6 below the bar chart it indicates, "Asymptomatic</p> <p>7 complications included caudal migration," correct?</p> <p>8 A. That's correct, that's written down.</p> <p>9 Q. So this IFU or package insert as you call it, in</p> <p>10 it Bard indicated that migration and specifically</p> <p>11 caudal migration of the G2 filter were a risk; is</p> <p>12 that right?</p> <p>13 A. Yes, that's written down as a caudal migration</p> <p>14 is on this package insert, assuming it was in the box</p> <p>15 at -- on that date.</p> <p>16 Q. And the same thing as tilt, correct?</p> <p>17 MR. ARBON: Objection to form.</p> <p>18 A. Let let's see, tilt is...</p> <p>19 Q. (BY MS. HELM) Right above it it says, of the 61</p> <p>20 retrievals, it says remember, "Resulted from</p> <p>21 inability to engage the filter apex with the Recovery</p> <p>22 Cone removal system due to filter tilt."</p> <p>23 A. That's correct.</p> <p>24 Q. Okay. Okay.</p> <p>25 And again, I understand you have to say assuming</p>
<p style="text-align: right;">Page 151</p> <p>1 correct?</p> <p>2 MR. ARBON: Objection, form.</p> <p>3 A. There might have been different papers written</p> <p>4 about different topics of filters. And some research</p> <p>5 may have been good, some research may need more</p> <p>6 research.</p> <p>7 Q. (BY MS. HELM) And in making your risk benefit</p> <p>8 analysis, you have to take that into consideration</p> <p>9 when you read that literature and evaluate it,</p> <p>10 correct?</p> <p>11 A. Yes, I have to decide the, how good the</p> <p>12 literature is.</p> <p>13 Q. Okay. Okay, I'm going to take you back to the</p> <p>14 IFU one more time and then we're probably going to be</p> <p>15 in pretty good shape.</p> <p>16 We've already discussed that on Page 2 under</p> <p>17 G -- under potential complications that movement or</p> <p>18 migration of the filter was identified as a risk; is</p> <p>19 that right?</p> <p>20 A. Yes, that's written down.</p> <p>21 Q. Okay. And we also discussed that tilt was a</p> <p>22 risk; is that right?</p> <p>23 A. That's written down.</p> <p>24 Q. And caudal migration is a risk?</p> <p>25 MR. ARBON: Objection, form.</p>	<p style="text-align: right;">Page 153</p> <p>1 this was in the box, but assuming that this is the</p> <p>2 IFU or package insert that accompanied the filter</p> <p>3 that you implanted in Ms. Kruse in 2009, you had the</p> <p>4 opportunity to review this IFU or package insert</p> <p>5 before you did the implant, correct?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. You were also aware of risks of the IVC</p> <p>8 filters from your training --</p> <p>9 A. Yes.</p> <p>10 Q. -- and fellowship, correct?</p> <p>11 A. Yes, because we already had one tilt that I was</p> <p>12 involved with.</p> <p>13 Q. Right, in your fellowship?</p> <p>14 A. Correct.</p> <p>15 Q. So you knew when you implanted Ms. Kruse's</p> <p>16 filter that tilt was a possible complication?</p> <p>17 A. Correct.</p> <p>18 Q. Did you discuss that with her?</p> <p>19 A. I'm sure we talked about several things when we</p> <p>20 gave consent.</p> <p>21 MR. ARBON: Objection, form and</p> <p>22 responsiveness.</p> <p>23 Q. (BY MS. HELM) Okay. You understand that Bard</p> <p>24 sales reps are not necessarily medically trained,</p> <p>25 correct?</p>

<p style="text-align: right;">Page 154</p> <p>1 A. I understand they're not doctors and they're  2 not -- and I've had them say that they're not giving  3 medical advice.  4 Q. Okay. And so when you speak with one or ask one  5 to be present during a procedure, you do it with the  6 understanding that they may be able to provide some  7 factual information about the product but they can't  8 provide medical recommendations or medical advice,  9 correct?  10 A. I understand they have limitations in what they  11 can say.  12 Q. Okay. And was -- was the reason that you  13 requested that -- would there be a record anywhere of  14 the request for the Bard representative to be present  15 at the retrieval of Ms. Kruse's filter?  16 A. No, it probably would have been verbal, not  17 written.  18 Q. Okay. And you don't know the representative's  19 name?  20 A. I do not know his name.  21 Q. Okay. And we've established today that it  22 wasn't recorded that he or she was in the room and  23 it's not anywhere in the medical record, correct?  24 A. That's correct.  25 Q. Okay.</p>	<p style="text-align: right;">Page 156</p> <p>1 BY MR. ARBON:  2 MR. ARBON: Yes, we have marked an  3 exhibit or plaintiff marked an Exhibit 2014  4 (sic), to the deposition, which is the G2 filter  5 permanent placement. There's a question as to  6 whether that was on our designation prior to the  7 deposition. Just for clarification, that  8 document was listed on our list as  9 BPVE01-149243. The copy that we've brought with  10 you and marked as an exhibit, bears a different  11 Bates number but it is the same document as what  12 was identified.  13 MR. NOVOTNY: Let me just for  14 clarification, you said 2014, it's 2114.  15 MR. ARBON: 2114, I'm sorry,  16 Exhibit 2114.  17 Q. (BY MR. ARBON) Doctor, I just want to take --  18 there's some statements or questions about the  19 meeting.  20 In our meeting, do you recall my referencing  21 that if I were to show you any document, I would need  22 you to sign a protective order?  23 A. Yes.  24 Q. And that's how that protective order got to you?  25 A. Yes.</p>
<p style="text-align: right;">Page 155</p> <p>1 A. And obviously those policies are directed by the  2 hospital, they're not my policies.  3 Q. Do you think it was important for Ms. Kruse to  4 go see another interventional radiologist about  5 having her filter removed?  6 A. I thought it appropriate at the time as opposed  7 to not getting treatment or seeing someone not  8 familiar with the filters.  9 MS. HELM: That's all I have.  10 Thank you.  11 VIDEOGRAPHER: Can we break for a  12 second? If you're going to continue, can we  13 break for a second to change media?  14 MR. ARBON: Sure.  15 VIDEOGRAPHER: Thank you.  16 MR. ARBON: And I promise this  17 won't be another...  18 VIDEOGRAPHER: We are off the  19 video record at 1735.  20 (Recess was taken.)  21 VIDEOGRAPHER: We are back on the  22 video record at 1738. Please proceed.  23  24  25 REDIRECT EXAMINATION</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. Do you recall that I had a copy of the  2 protective order with me?  3 A. I don't recall. You might have.  4 Q. Okay. And then no e-mails were actually shown  5 to you or handed to you or -- during that meeting,  6 correct?  7 A. Nothing was given to me --  8 MS. HELM: Object to the form,  9 leading.  10 (Court reporter interrupted for clarification.)  11 A. There was no papers given from the attorney to  12 me to hold.  13 MS. HELM: Tom, you don't need to  14 ask these questions.  15 MR. ARBON: Fair enough.  16 MS. HELM: And I'll clarify it at  17 the end -- go ahead, I'll clarify it at the end.  18 Q. (BY MR. ARBON) Can you get the IFU in front of  19 you again, please?  20 MR. NOVOTNY: That's a pretty  21 popular document.  22 MR. ARBON: It is. Today it is.  23 Q. (BY MR. ARBON) And do you have the IFU, sir?  24 A. Yes.  25 Q. And that is 2109?</p>

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<p>1 MS. HELM: It is.</p> <p>2 Q. (BY MR. ARBON) Could you go to Page 1 of the</p> <p>3 document, sir, you see a subsection --</p> <p>4 A. Yes, I see.</p> <p>5 Q. See a subsection at the bottom marked E?</p> <p>6 A. Okay.</p> <p>7 Q. There's a section marked E?</p> <p>8 A. Okay, yes, warnings.</p> <p>9 Q. Warnings. What does warnings mean to you as a</p> <p>10 physician when you're reading an instruction for use?</p> <p>11 MS. HELM: Objection to form.</p> <p>12 A. Warning would mean for me something that</p> <p>13 requires caution.</p> <p>14 Q. (BY MR. ARBON) Something that could be related</p> <p>15 to the safety of the product; is that fair?</p> <p>16 MS. HELM: Objection to the form.</p> <p>17 You're leading.</p> <p>18 A. Not, not necessarily. It could be a warning of</p> <p>19 how to deploy the product.</p> <p>20 Q. (BY MR. ARBON) How do you, Doctor, when reading</p> <p>21 an instruction for use, or an IFU, does the term</p> <p>22 warnings have any particular import to you?</p> <p>23 A. It would -- you would want to know what warnings</p> <p>24 were to not make a mistake.</p> <p>25 Q. What's No. 6 of the warnings?</p>	<p>1 right?</p> <p>2 MS. HELM: Object to the form.</p> <p>3 A. I'm the doctor, correct.</p> <p>4 Q. (BY MR. HELM) You as the doctor who is utilizing</p> <p>5 these instructions and utilized instructions like</p> <p>6 this for selecting the G2 filter that was placed in</p> <p>7 Ms. Kruse, are relying on this information to be</p> <p>8 accurate, correct?</p> <p>9 MS. HELM: Object to the form.</p> <p>10 A. The package insert should be correct.</p> <p>11 Q. (BY MR. HELM) When there's a reference in the</p> <p>12 package insert that says, filter fracture is a known</p> <p>13 complication but most cases, however, have been</p> <p>14 reported without -- without any adverse clinical</p> <p>15 sequella; does that to you as a doctor give you some</p> <p>16 degree of severity that is being associated to</p> <p>17 fracture?</p> <p>18 MS. HELM: Object to the form.</p> <p>19 A. Fix -- I'm not an expert, but filter fracture</p> <p>20 sounds bad to me.</p> <p>21 Q. (BY MR. ARBON) Okay. But if that's modified by</p> <p>22 saying the patient doesn't suffer any adverse</p> <p>23 sequella, does that have any affect on your view of</p> <p>24 that warning?</p> <p>25 MS. HELM: Object to the form.</p>
Page 159	Page 161
<p>1 A. Number 6, "Filter fracture is a known</p> <p>2 complication of vena cava filters. There have been</p> <p>3 reports of embolization of vena cava filter fragments</p> <p>4 resulting in retrieval of the fragment using</p> <p>5 intravascular and/or surgical techniques. Most cases</p> <p>6 a filter fracture, however, have been reported</p> <p>7 without any adverse clinical sequella."</p> <p>8 Q. What does, reported without any adverse clinical</p> <p>9 sequella mean to you?</p> <p>10 A. I didn't write this document, but I would</p> <p>11 imagine it means the filter fracture fragments can be</p> <p>12 removed and the patient does well.</p> <p>13 Q. Would you consider reported cases of patients</p> <p>14 having pieces of a G2 filter embolize into their</p> <p>15 heart and not be retrievable, even through open heart</p> <p>16 procedures, to be an adverse clinical sequella?</p> <p>17 MS. HELM: Object to the form, it</p> <p>18 calls for an expert opinion. It doesn't have</p> <p>19 anything to do with Ms. Kruse.</p> <p>20 A. I can only tell you about Ms. Kruse. Luckily</p> <p>21 she didn't have a fracture. And that was one thing I</p> <p>22 was concerned about on retrieval, is if I tried too</p> <p>23 hard, I could break the filter.</p> <p>24 Q. (BY MR. ARBON) Well, Doctor, these instructions</p> <p>25 are directed to you, you're the target audience here,</p>	<p>1 A. That would mean sometimes there's -- sometimes</p> <p>2 the procedure went well and sometimes it requires a</p> <p>3 lot more.</p> <p>4 Q. (BY MR. ARBON) Okay. And I promise, Doctor, I'm</p> <p>5 not doing this just to delay, but No. 7 is the next</p> <p>6 one on the list of warnings. Would you read that for</p> <p>7 me?</p> <p>8 A. Number 7, Page 2. Movement of -- Movement or</p> <p>9 migration of the filter is a known complication of</p> <p>10 vena cava filters. This may cause -- may be caused</p> <p>11 by placement in IVCs with diameters exceeding the</p> <p>12 appropriate labeled dimensions specified in the IFU.</p> <p>13 Migration of filters to the heart or lungs have been</p> <p>14 reported in association with improper deployment,</p> <p>15 deployment into clots and/or dislodgement due to</p> <p>16 large clot burdens.</p> <p>17 Q. Does that warning about migration say anything</p> <p>18 that death -- about deaths having occurred from</p> <p>19 filter migration?</p> <p>20 MS. HELM: Object to form.</p> <p>21 A. That line, there's two things I would say</p> <p>22 regarding that, now that you brought it up. Number</p> <p>23 1, that's why I did a CT scan beforehand because I</p> <p>24 knew if the filter -- if the IVC was too big, it</p> <p>25 could -- it could migrate to the heart, so that's the</p>

<p style="text-align: right;">Page 162</p> <p>1 first comment.</p> <p>2 The second comment is: There's no word death in</p> <p>3 that No. 7 statement.</p> <p>4 Q. (BY MR. ARBON) Now, if Bard were aware that</p> <p>5 filter migration --</p> <p>6 (Court reporter interrupted for clarification.)</p> <p>7 Q. If Bard were aware that filter migration</p> <p>8 utilizing the Recovery and the G2 filter had caused</p> <p>9 deaths by migration to the heart, would that be</p> <p>10 important information to include in that warning?</p> <p>11 MS. HELM: Object to the form, it</p> <p>12 calls for speculation and lacks foundation.</p> <p>13 A. I don't know what Bard would consider important.</p> <p>14 For me, the more I know about the filter, the better.</p> <p>15 Q. (BY MR. ARBON) Let me ask you -- we'll put it in</p> <p>16 context, Doctor.</p> <p>17 When they're discussing filter fracture, Bard in</p> <p>18 its warnings, felt it necessary to state that most</p> <p>19 cases of filter fracture have been reported without</p> <p>20 any adverse clinical sequella. Is there any other</p> <p>21 purpose for including that information, to --</p> <p>22 departing that information in IFU then to give the</p> <p>23 information to the utilizing physician as to their</p> <p>24 view of the severity of fracture?</p> <p>25 MS. HELM: Object to the form.</p>	<p style="text-align: right;">Page 164</p> <p>1 A. Yes.</p> <p>2 Q. Did she have proper deployment?</p> <p>3 A. Yes.</p> <p>4 Q. Did you deploy this filter into a clot?</p> <p>5 A. No.</p> <p>6 Q. Did you see, when you attempted to retrieve the</p> <p>7 filter, any indication of a large clot burden in that</p> <p>8 filter?</p> <p>9 A. No.</p> <p>10 Q. Can you tell me then why that filter has</p> <p>11 migrated?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 A. I don't know why the filter -- the filter's not</p> <p>14 where I placed it, that's all I can tell you.</p> <p>15 Q. (BY MR. ARBON) No doubt it's migrated, correct?</p> <p>16 A. Correct, from where I positioned it --</p> <p>17 Q. And none of -- and none of the conditions that</p> <p>18 the warning provided by Bard regarding the G2 about</p> <p>19 how migrations occur relate to Ms. Kruse's case, do</p> <p>20 they?</p> <p>21 MS. HELM: Object to the form,</p> <p>22 mischaracterizes the document.</p> <p>23 A. I'm not sure. Repeat the question, I'm not</p> <p>24 sure.</p> <p>25 Q. (BY MR. ARBON) None of these listed warnings</p>
<p style="text-align: right;">Page 163</p> <p>1 Calls for speculation.</p> <p>2 A. I don't know what their intent was when they say</p> <p>3 most cases, I'm not sure what the point was.</p> <p>4 Q. (BY MR. ARBON) Now, if there were deaths that</p> <p>5 were known to have been associated with migration of</p> <p>6 the filter to the heart, if they're going to tell you</p> <p>7 the sequella of a fracture -- what the sequella from</p> <p>8 the fractures were, should there be some indication</p> <p>9 of as to what the sequella from a migration to the</p> <p>10 heart was?</p> <p>11 MS. HELM: Object to the form.</p> <p>12 MR. NOVOTNY: If you're asking for</p> <p>13 standard of care, should there be, he's not --</p> <p>14 he's not giving a standard of care opinion the</p> <p>15 way the question was phrased.</p> <p>16 MR. ARBON: No, I'm asking as a</p> <p>17 physician reading the information, is that what</p> <p>18 he would anticipate?</p> <p>19 MS. HELM: Same objection.</p> <p>20 A. I would expect the IFU to state the</p> <p>21 complications that exist for their product.</p> <p>22 Q. (BY MR. ARBON) Now let me ask under this section</p> <p>23 warnings, where we talk about movement or migration</p> <p>24 of the filter: Was Ms. Kruse's diameter</p> <p>25 appropriate -- of an appropriate dimension?</p>	<p style="text-align: right;">Page 165</p> <p>1 that Bard provided in the IFU for the G2 filters that</p> <p>2 she has, which reference the causes of migration,</p> <p>3 none of those reference causes relate to Ms. Kruse's</p> <p>4 case, do they?</p> <p>5 MS. HELM: Object to the form.</p> <p>6 A. The causes listed in No. 7 -- do not appear to</p> <p>7 occur, have occurred in Ms. Kruse's case from what I</p> <p>8 can tell.</p> <p>9 Q. (BY MR. ARBON) I'm sorry to do this but in light</p> <p>10 of the objection, sir, let me ask you: After review</p> <p>11 of the warning No. 7 from the Bard IFU, did any of</p> <p>12 the causes that Bard has listed related to the cause</p> <p>13 of migration occur in Ms. Kruse?</p> <p>14 MS. HELM: Object to the form.</p> <p>15 A. Let's see, the No. 7 says the IVC diameter is an</p> <p>16 issue and that seemed to be appropriate. And that</p> <p>17 filters have migrated, so that's a known</p> <p>18 complication. And there was no improper deployment,</p> <p>19 that I could tell and there's no clots present. So</p> <p>20 as far as I can tell, all those things seemed</p> <p>21 appropriate for our particular case and -- but the</p> <p>22 filter migrated.</p> <p>23 Q. (BY MR. ARBON) Did any of those conditions that</p> <p>24 are listed there as causes for migration, occur in</p> <p>25 Ms. Kruse?</p>

<p style="text-align: right;">Page 166</p> <p>1 MS. HELM: Object to the form.</p> <p>2 A. For Ms. Kruse, there was no clot and the IVC was</p> <p>3 the appropriate size, so I would not have predicted</p> <p>4 any problems with migration.</p> <p>5 Q. (BY MR. ARBON) If you look down on Page 2, sir,</p> <p>6 of the IFU, Section G, just below middle of the page?</p> <p>7 A. G, potential complications.</p> <p>8 Q. Right. What are potential complications mean to</p> <p>9 you as a physician to whom IFUs like this are</p> <p>10 directed?</p> <p>11 A. To me, that would mean in the experience of</p> <p>12 other doctors, events that weren't expected but could</p> <p>13 be predicted happen.</p> <p>14 Q. Okay. And is that -- do you look to potential</p> <p>15 complications, that heading, when you're reviewing</p> <p>16 IFUs?</p> <p>17 MS. HELM: Object to the form.</p> <p>18 A. The -- it's always best to know the</p> <p>19 complications of a procedure.</p> <p>20 Q. (BY MR. ARBON) Similarly, do you look for, when</p> <p>21 you're reading IFUs, the warning section?</p> <p>22 A. In the review literature, I look for</p> <p>23 complications.</p> <p>24 Q. Okay. And also, would you look for a section</p> <p>25 headed warnings?</p>	<p style="text-align: right;">Page 168</p> <p>1 A. Okay.</p> <p>2 Q. Or the complications heading, that's the middle</p> <p>3 of the page, does caudal migration appear anywhere in</p> <p>4 those sections of the IFU?</p> <p>5 A. Page 2 says migration. I don't see the word</p> <p>6 caudal migration written, at the top on No. 7. Under</p> <p>7 potential complication, I see the word migration, I</p> <p>8 don't see the word caudal.</p> <p>9 Q. Okay. So is it true that the only place that</p> <p>10 the term caudal migration appears is on Page 4 where</p> <p>11 it is noted as a finding in the clinical experience</p> <p>12 discussion of the one study that's referenced?</p> <p>13 A. On Page 4, I see the word caudal migration, 10</p> <p>14 cases.</p> <p>15 Q. Under what heading?</p> <p>16 A. "Asymptomatic complications include," under the</p> <p>17 heading of, "Clinical Experience."</p> <p>18 Q. Clinical experience section is not a warning</p> <p>19 section, is it?</p> <p>20 MS. HELM: Object to the form.</p> <p>21 A. Well, it talks about bad things that can happen</p> <p>22 like filter tilting but it's not labeled warning.</p> <p>23 Q. (BY MR. ARBON) All right. Filter tilts wasn't</p> <p>24 brought up in the warnings or the complication</p> <p>25 section, was it?</p>
<p style="text-align: right;">Page 167</p> <p>1 A. I would look for -- a section warning, I would</p> <p>2 want to read.</p> <p>3 Q. Draws your attention as a physician --</p> <p>4 A. Right.</p> <p>5 Q. -- to those sections, right?</p> <p>6 MS. HELM: Object to the form.</p> <p>7 A. Correct.</p> <p>8 Q. (BY MR. ARBON) Do --</p> <p>9 A. Warning sounds important as a physician.</p> <p>10 Q. In reading IFUs, does the heading, "Warnings,"</p> <p>11 cause you to pay attention to that section?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 A. I would think the warnings written would be</p> <p>14 helpful.</p> <p>15 Q. (BY MR. ARBON) And when you see a heading,</p> <p>16 "Potential Complications," how does that affect what</p> <p>17 you're reading of an IFU?</p> <p>18 A. That these are complications that one should</p> <p>19 actually try and look out for.</p> <p>20 Q. Under warnings section in this IFU and under the</p> <p>21 potential complications section, does the term caudal</p> <p>22 migration appear anywhere?</p> <p>23 A. I'm sorry, say that again.</p> <p>24 Q. Under the warning section, that's up at the top</p> <p>25 of the page.</p>	<p style="text-align: right;">Page 169</p> <p>1 MS. HELM: Object to the form.</p> <p>2 A. You know, I didn't make this document, so I'm</p> <p>3 not sure what they --</p> <p>4 Q. (BY MR. ARBON) And I understand.</p> <p>5 A. -- thought. But let's see, if you're talking</p> <p>6 about Page 1, warning E. On Page 1, I don't see the</p> <p>7 word tilting.</p> <p>8 Q. And I'm not to belabor but you mention on Page</p> <p>9 2, do you see it under potential complications?</p> <p>10 A. I see in the Section G on Page 2, I don't see</p> <p>11 the word tilt.</p> <p>12 (Exhibit No. 2126, marked for identification.)</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>



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 21 Q. (BY MR. ARBON) Do you recall how long your  
 22 retrieval procedure lasted?  
 23 A. Long enough to decide not to retrieve it and  
 24 come up with an alternate plan.  
 25 MS. HELM: Let me just -- I may

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1 have it.  
 2 A. But, yeah, the anesthesia record would easily  
 3 tell the time beginning and ending.  
 4 Q. (BY MR. ARBON) What I'm going to hand you doctor  
 5 are two pages from medical record. And those pages  
 6 are Kruse -- are Bates stamped KRUSEC\_MLMH\_MDR 00058  
 7 and 59.  
 8 (Exhibit No. 2127, marked for identification.)  
 9 Q. And I marked them at 2127.  
 10 MS. HELM: Actually, what you've  
 11 marked, just so the record is clear, is 57, 58,  
 12 59 and 60, because it's printed double sided.  
 13 MR. ARBON: And I apologize --  
 14 MS. HELM: It's fine, it's fine,  
 15 I've got it --  
 16 MR. ARBON: -- it's a double sided  
 17 copy.  
 18 Q. (BY MR. ARBON) Looking at the documents and  
 19 specifically the anesthesia record that's recorded  
 20 there, can you tell me how long your procedure was  
 21 with regard to retrieval -- attempted retrieval of  
 22 the filter?  
 23 A. Let's see, I have two-pieces of paper. 2127,  
 24 it's on the 7th of April. And if I can read the  
 25 handwriting right, it may start at 0930 and it may

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1 end at 1126.  
 2 Q. Just shy of two hours?  
 3 MS. HELM: Object to the form.  
 4 A. From 9 a.m. to 11, almost, two hours.  
 5 Q. (BY MR. ARBON) During that two hours --  
 6 A. No, that's the anesthesia record, obviously.  
 7 Q. Sure. But during that period of time, what  
 8 were -- what was your -- what were you attempting to  
 9 do?  
 10 A. Well, anesthesia would provide conscious  
 11 sedation and get the patient appropriate for the  
 12 procedure. And then when they were adequate for the  
 13 procedure to begin, then we would access the neck and  
 14 then attempt to retrieval of the filter until we  
 15 thought it was time to stop. Which would have been,  
 16 it looks like roughly 11:26.  
 17 Q. And throughout that time, those were your  
 18 attempts to trying and retrieve this filter?  
 19 MS. HELM: Object to the form.  
 20 A. That was the, it looks like the anesthesia  
 21 duration for the case.  
 22 Q. (BY MR. ARBON) When you said you elected not to  
 23 attempt the loop procedure, you reference at one  
 24 point, I think you had mentioned, time of procedure;  
 25 is that what you were referencing?

<p style="text-align: right;">Page 174</p> <p>1 A. No, the reason I had stopped was for many 2 reasons; the duration of the case, the complexity of 3 the case, the complications that could occur from 4 doing more advanced procedure, all of those things 5 which were -- influenced my decision. 6 Q. What are the complications that you were aware 7 of that could have occurred had you tried more 8 advanced procedure at that time? 9 A. Numerous, including death of the patient. 10 Q. Was rupture of the IVC one of those potential 11 complications? 12 MS. HELM: Object to the form. 13 A. I believe that's why I documented that somewhere 14 in one of my records. 15 Q. (BY MR. ARBON) Okay. So certainly when you 16 discussed the complications as is noted in your, the 17 file, post op from the retrieval percentage, was the 18 fact that a percutaneous -- another percutaneous 19 procedure had the risk of tearing the IVC filter, was 20 that discussed with Ms. Kruse? 21 MS. HELM: Object to the form. 22 A. Having already presented the information once of 23 the complications, I don't think I would have told 24 her what are the complications, another doctor would 25 have told her.</p>	<p style="text-align: right;">Page 176</p> <p>1 remove it. 2 Q. Given the condition of the filter and the 3 difficulty you had trying to remove it, would 4 rupturing the IVC be one of the potential problems 5 that could can occur with a percutaneous retrieval of 6 a filter? 7 MS. HELM: Object the form, calls 8 for speculation. 9 A. IVC damage or rupture was known preceding that 10 retrieval so I think your answer is correct. 11 Q. (BY MR. ARBON) Okay. If we can go to -- I'm 12 really winding down, I promise you. 13 2122, the note. 14 (Discussion off the record.) 15 Q. Counsel defendants noted that there's a 16 typewritten header, for a better term, on that 17 exhibit; do you see it, sir? 18 A. I see her name at the top with a type of a ID, 19 identifying number. 20 Q. Do you know how that got on there? 21 A. I'm not in charge of the hospital record 22 keeping. 23 Q. You're not a custodian of those records, right? 24 A. I'm not the custodian, that's true, the hospital 25 is.</p>
<p style="text-align: right;">Page 175</p> <p>1 Q. (BY MR. ARBON) And I guess that's not what 2 I'm... 3 A. Then I, if I heard your question right. If you 4 asked what would a doctor tell her on the fir -- I 5 don't know what they would tell her. 6 Q. No, I'm talking about what did you tell -- 7 "Unable to retrieve filter, discussed options." When 8 you discussed options, did you discuss -- well, did 9 you explain to her why you stopped when you did? 10 A. That we couldn't retrieve the filter and it was 11 tilted, yes, told her that. 12 Q. Okay. 13 A. And it had migrated. 14 Q. In discussing options did you discuss then a 15 open procedure might be an option for needing to get 16 this out? 17 MS. HELM: Object to the form. 18 A. No, we didn't discuss all of the options 19 available to her. 20 Q. (BY MR. ARBON) You just discussed you should see 21 another doctor, is that the extent of the options? 22 A. No, we discussed that we tried to retrieve it 23 and then in order to avoid the complications that we 24 had discussed about before the procedure, we stopped. 25 And that she would need additional procedure done to</p>	<p style="text-align: right;">Page 177</p> <p>1 Q. 2121 and -- well, let me just list off, 2121, 2 2115, these are all hospital records, correct, that 3 we marked? 4 A. Those are hospital records that are produced by 5 different software. One's a physical chart -- one's 6 a physical chart and the other is a computer program. 7 Q. Okay. 8 A. And this is a handwritten note told to scan in 9 to the patient's record so it would be there 10 permanently. 11 Q. Okay. 12 A. So there was emphasis on this note. 13 Q. So it was scanned in so that's -- 14 A. I -- 15 (Court reporter interrupted for clarification.) 16 Q. The scanning it in is how it got into the file? 17 A. Let me retract that. I don't know how it got 18 into the file, but it is part of the permanent file 19 and under my direction to be a part of the permanent 20 file. 21 Q. Were you present when miss -- is it Bieck, 22 Bieck? 23 A. Bieck. 24 Q. Made this phone call that's documented under 25 7/7/11?</p>

<p style="text-align: right;">Page 178</p> <p>1 A. No, I would not have been present on the phone  2 with her.  3 Q. Okay. Do you know who John Mayors is or Majors  4 (sic?)  5 A. No.  6 Q. Majerus?  7 A. I would assume Ms. Bieck and Ms. Kruse would  8 know who that is.  9 Q. All right. That's not an interventional  10 radiologist that you had Ms. Bieck recommend, is it?  11 A. I don't know who John Mayors (sic) is.  12 Q. Okay. That's her primary care doctor, if that  13 helps, Doctor, I believe.  14 A. Okay. Let's see, so that would -- but our  15 instructions to her were to go to Grand Island or  16 Lincoln and that was our instructions and help  17 facilitate that.  18 Q. Whose handwriting is the note at the bottom?  19 A. That's Joyce Bieck's handwriting also. And it's  20 my signature above it, because I knew it was  21 important to try to document as much of our  22 communication as we could.  23 Q. Okay. But you weren't present when she actually  24 spoke to Ms. Kruse?  25 A. No, I was not on the phone when she spoke to</p>	<p style="text-align: right;">Page 180</p> <p>1 MS. HELM: Object to the form.  2 Calls for speculation.  3 A. Well, it's, like, two questions. One, she could  4 get it retrieved, but would she have necessarily  5 represented to the -- to the medical provider,  6 possibly not. I mean, that's a complicated question.  7 Q. (BY MR. ARBON) Let me try a different question.  8 If when you Ms. Kruse -- you saw Ms. Kruse in  9 2011, you had done imaging that indicated the filter  10 was still in the position you had placed it in, would  11 there have been a need to retrieve it?  12 MS. HELM: Object to form.  13 A. If it were in the same place -- I don't know  14 what their primary care doctor would have done,  15 because I didn't order that x-ray so I don't know  16 what they would have done.  17 Q. If you had not observed the filter -- in April  18 of 2011, if you had not observed that her G2 filter  19 had caudally migrated and tilted, would you have  20 recommend -- would you be recommending that she have  21 another interventional radiologist evaluate her for  22 retrieval at that time?  23 MS. HELM: Object to the form.  24 A. So if your question is -- repeat your question.  25 Q. (BY MR. ARBON) I'll just restate it.</p>
<p style="text-align: right;">Page 179</p> <p>1 Ms. Kruse.  2 Q. Okay. Doctor is there any doubt in your mind  3 that there was a Bard sales representative present  4 during the retrieval process, or attempted retrieval  5 of Ms. Kruse's filter?  6 MS. HELM: Object to the form.  7 A. I believe a rep was present there.  8 Q. (BY MR. ARBON) If Ms. Kruse's G2 filter had not  9 caudally migrated and tilted in the bifurcation,  10 would she had needed any follow-up or referral to any  11 interventional radiologist?  12 MS. HELM: Object to form.  13 A. If --  14 MS. HELM: Calls for speculation.  15 A. My honest answer is I don't know. Would we be  16 here today, probably not.  17 Q. (BY MR. ARBON) Okay. But let me rephrase the  18 question.  19 MS. HELM: I'm going to object to  20 the responsiveness.  21 Q. (BY MR. ARBON) If the G2 filter that was  22 implanted in Ms. Kruse in '09 had not migrated  23 caudally and tilted in -- as discovered in 2011,  24 would she have needed any follow-up for a retrieval  25 in 2011?</p>	<p style="text-align: right;">Page 181</p> <p>1 Doctor, was the only reason you were  2 recommending that she get a second opinion about  3 retrieval is because the filter had migrated  4 caudally, tilted and you couldn't get it out?  5 A. I referred her because my attempt at retrieval,  6 I couldn't retrieve it.  7 Q. And you couldn't retrieve it because it was  8 migrated and tilted, correct?  9 MS. HELM: Object to the form.  10 A. I believe that's accurate.  11 MR. ARBON: I'll pass.  12 MS. HELM: I have very couple  13 follow-ups.  14 CROSS EXAMINATION  15 BY MS. HELM:  16 Q. Doctor, I'm not going to take you through the  17 IFU again, but you would agree with me that it's  18 important for you to read the entire IFU; would you  19 not?  20 A. Yes, I think more information would be helpful.  21 Q. Okay. And we discussed previously that in the  22 clinical experience section of the IFU, it  23 specifically addressed caudal migration and tilt,  24 correct?  25 A. The IFU has the word migration in it and I think</p>

<p style="text-align: right;">Page 182</p> <p>1 it did have the word tilt in it, yes.</p> <p>2 Q. Okay. And just so our record's clear: If</p> <p>3 you'll look on Page 4 under clinical experience it's</p> <p>4 talking about experience with filters that have been</p> <p>5 implanted. And down below the bar graph it says that</p> <p>6 some of the filters, they have an inability to engage</p> <p>7 the filter apex with the Recovery Cone Removal System</p> <p>8 due to filter tilt, correct?</p> <p>9 A. I remember you saying that. Where exactly --</p> <p>10 Q. Right below the bar chart.</p> <p>11 A. Okay, yeah. Let's see, it says three technical</p> <p>12 failures of retrieval resulted from inability to</p> <p>13 engage the filter on apex.</p> <p>14 Q. With the Recovery Cone Removal System due to</p> <p>15 filter tilt.</p> <p>16 A. Correct.</p> <p>17 Q. Okay. And again, below that in the sentence</p> <p>18 starting asymptomatic complications, Bard again told</p> <p>19 you there had been instances of caudal migration,</p> <p>20 correct?</p> <p>21 A. It does state --</p> <p>22 MR. ARBON: Objection to form.</p> <p>23 A. -- the asymptomatic complications include caudal</p> <p>24 migration, No. 10.</p> <p>25 Q. (BY MS. HELM) Okay. And you would agree with me</p>	<p style="text-align: right;">Page 184</p> <p>1 have. Thank you.</p> <p>2 MR. ARBON: If you can just let me</p> <p>3 see that document, I want to see if there's</p> <p>4 something on there.</p> <p>5 (Witness handing to Mr. Arbon.)</p> <p>6 FURTHER REDIRECT EXAMINATION</p> <p>7 BY MR. ARBON:</p> <p>8 Q. Would your attempts pretty much -- once you</p> <p>9 began your procedure, after she's been anesthetized,</p> <p>10 how long after you stop would anesthesia stop</p> <p>11 normally?</p> <p>12 A. Let's see the record to review. Tell me your</p> <p>13 question one more time.</p> <p>14 Q. I guess I'm just trying to figure out, they</p> <p>15 stopped the anesthesia -- anesthesia ended at 11:26;</p> <p>16 am I reading that correctly?</p> <p>17 A. She has that written down as the time of a vital</p> <p>18 sign, but I don't know if she is administering it, a</p> <p>19 sedation or not.</p> <p>20 Q. Okay. Can you give me the last four digits of</p> <p>21 the Bates number on that page you're looking at now</p> <p>22 please, sir?</p> <p>23 No, the one, just the Bates number. Let me show</p> <p>24 you. I'll do it this way, just try and speed it up.</p> <p>25 If that's possible.</p>
<p style="text-align: right;">Page 183</p> <p>1 that caudal migration is a type of migration,</p> <p>2 correct?</p> <p>3 A. I think that's reasonable.</p> <p>4 Q. Okay. And then if you would refer to the last</p> <p>5 exhibit, 2127.</p> <p>6 This is not a record of how long you attempted</p> <p>7 to retrieve the filter, is it?</p> <p>8 A. This is the anesthesia conscious sedation</p> <p>9 record.</p> <p>10 Q. Okay. So it's not a record of how long you</p> <p>11 attempted to retrieve the filter, is it?</p> <p>12 A. Not necessarily minute by minute.</p> <p>13 Q. Okay. In fact, this is the beginning of when</p> <p>14 the patient was put under sedation until when the</p> <p>15 sedation was stopped, correct?</p> <p>16 A. Actually, to be precise at 9:30 is when vitals</p> <p>17 were begun and then it looks like the administration</p> <p>18 of medication was 14 minutes later. So this, all I</p> <p>19 can say is this is the anesthesia record of the case.</p> <p>20 Q. Okay. So you didn't start your retrieval</p> <p>21 attempt at 9:30, did you?</p> <p>22 A. Not necessarily. I wouldn't -- I didn't</p> <p>23 document the time of beginning and end, so. But this</p> <p>24 is an anesthesia record, not my record.</p> <p>25 MS. HELM: Okay, that's all I</p>	<p style="text-align: right;">Page 185</p> <p>1 MS. HELM: 60.</p> <p>2 Q. (BY MR. ARBON) Yeah, Page 60, Doctor, which is</p> <p>3 part of the record.</p> <p>4 A. Okay.</p> <p>5 Q. There's an indication in there as to when your</p> <p>6 procedure started, correct?</p> <p>7 A. Let's see, this is an anesthesia note,</p> <p>8 handwritten nursing note at the top.</p> <p>9 Timeout done, patient understand verbalize good</p> <p>10 understanding -- patient verbalized good</p> <p>11 understanding of the procedure. Right neck was</p> <p>12 prepped by the Bieck, so that would be the tech.</p> <p>13 Patient draped and Dr. Smith begins procedure at</p> <p>14 9:40, roughly.</p> <p>15 So that would -- that sounds like the beginning</p> <p>16 of the procedure. Which would begin first with</p> <p>17 preparing the neck for the procedure. And then it</p> <p>18 says, "Sedation started." So that seems helpful on</p> <p>19 the time.</p> <p>20 Q. This may be more helpful, Doctor.</p> <p>21 A. Oh.</p> <p>22 Q. Am I this dumb?</p> <p>23 (Discussion off the record.)</p> <p>24 Q. Everybody can answer this one for me. Doctor --</p> <p>25 A. I mean, this isn't my record so it's hard for me</p>

<p style="text-align: right;">Page 186</p> <p>1 to know.</p> <p>2 Q. Wait a minute, let me strike my last question.</p> <p>3 Let me show you page 2127.</p> <p>4 A. Okay, let's see, Exhibit 2127.</p> <p>5 Q. And let's just look right here. Does it say</p> <p>6 what time the procedure started?</p> <p>7 A. The No. 1 procedure time, 045, but I'm not sure</p> <p>8 what that means, but that's what she's written there.</p> <p>9 Q. See the line that says procedure start time?</p> <p>10 A. That's what it says, yes.</p> <p>11 Q. And what does it say?</p> <p>12 A. 0945.</p> <p>13 Q. And it says end time, correct?</p> <p>14 A. That's correct, it says end time 11:15 and her</p> <p>15 vitals signs extend to 11:27.</p> <p>16 Q. Based on your understanding of anesthesia</p> <p>17 records, Doctor, does it appear that the actual</p> <p>18 interventional procedure went from 9:45 to 11:15?</p> <p>19 A. I would -- I could say that the procedure in</p> <p>20 total went from 9:45, I -- I don't know the exact</p> <p>21 timing of when the needle stick occurred. I would</p> <p>22 assume it's close to that.</p> <p>23 Q. Doctor, and my last line of questioning here,</p> <p>24 wonderful IFU again.</p> <p>25 In that section counsel keeps referring to,</p>	<p style="text-align: right;">Page 188</p> <p>1 Q. Then what she's also pointed to you is in</p> <p>2 referencing the findings of that study. Of the</p> <p>3 people of which there were attempted retrievals they</p> <p>4 note there were 10 caudal migrations, that they call</p> <p>5 asymptomatic complication, correct?</p> <p>6 A. That's interesting, I'm not sure how to</p> <p>7 interpret that actually. If clinical experience is</p> <p>8 talking about removal, then that means they would</p> <p>9 have already migrated, so I'm not quite sure.</p> <p>10 So repeat your question, so I understand 'cause</p> <p>11 I'm not --</p> <p>12 Q. I'm just trying to get you caught up with me on</p> <p>13 some of the facts that I'm seeing this in this</p> <p>14 document.</p> <p>15 A. Yeah, okay.</p> <p>16 Q. This is not instructing you about a</p> <p>17 complicate -- intention of this section is not to</p> <p>18 discuss a complication or a warning, it's to describe</p> <p>19 the findings of a study that was conducted to assess</p> <p>20 the safety of the removal of a G2; is that a fair</p> <p>21 assessment?</p> <p>22 MS. HELM: Object to the form.</p> <p>23 Calls for speculation.</p> <p>24 A. I'm not sure what their intent was. I think it</p> <p>25 means that they're providing a study that talks about</p>
<p style="text-align: right;">Page 187</p> <p>1 clinical experience, where it's on Page 4, where it's</p> <p>2 discussing a clinical study involving 100 patients</p> <p>3 was conducted to assess the safety of removal of the</p> <p>4 G2, that's the heading or lead into the section?</p> <p>5 A. I'm sorry, repeat the question one more time.</p> <p>6 Q. Sure. Clinical experience section --</p> <p>7 A. Okay.</p> <p>8 Q. -- that's been referenced by the defense</p> <p>9 counsel. A clinical study involving 100 patients was</p> <p>10 conducted to access the safety of removal of the G2</p> <p>11 filter, do you see that line? Did I read that</p> <p>12 correctly?</p> <p>13 A. Let's see, can you -- at the top, okay. I see.</p> <p>14 Now that I know you're at the top, can you repeat the</p> <p>15 question one more time?</p> <p>16 Q. Okay. You've been referred repeatedly to the</p> <p>17 clinical experience section of the instructions for</p> <p>18 use. The first sentence of which is a clinical study</p> <p>19 involving 100 patients was conducted to assess the</p> <p>20 safety of removal of the G2 filter, is -- did I read</p> <p>21 that correctly?</p> <p>22 A. Yes.</p> <p>23 Q. So this section is describing a study done that</p> <p>24 Bard said was done for safety of removal, correct?</p> <p>25 A. That's what's written in the first sentence.</p>	<p style="text-align: right;">Page 189</p> <p>1 the safety of the removal of the filter and what bad</p> <p>2 things can happen.</p> <p>3 Q. (BY MR. ARBON) All right. Now, in it where</p> <p>4 counsel's pointed you out to, three failures resulted</p> <p>5 from the inability to engage the filter apex with the</p> <p>6 Recovery Cone system due to filter tilt, leading to</p> <p>7 embedding. Do you see that paragraph?</p> <p>8 A. Yes, I see that.</p> <p>9 Q. Okay. This is the same IFU that tells you to</p> <p>10 only retrieve utilizing the Recovery Cone, correct?</p> <p>11 MS. HELM: Object to the form,</p> <p>12 mischaracterizes the document and the prior</p> <p>13 testimony.</p> <p>14 A. I've seen that this literature or this Exhibit</p> <p>15 2109 only talks about the retrieval cone technique.</p> <p>16 Q. (BY MR. ARBON) And then what instruction does</p> <p>17 this IFU give for those three patients or patients</p> <p>18 like them where tilt has embedded the filter and you</p> <p>19 can't get it out with the Recovery Cone, what help</p> <p>20 does this IFU give you?</p> <p>21 A. I don't know what the intent of the help -- I</p> <p>22 don't know what the intent of the -- that section was</p> <p>23 for.</p> <p>24 Q. Okay. The IFU doesn't instruct you how to</p> <p>25 handle that circumstance, does it? How to do a</p>



<p style="text-align: right;">Page 190</p> <p>1 retrieval where the cone can't engage?</p> <p>2 A. You know, honestly I don't know what an IFU is</p> <p>3 supposed to cover and what it's not supposed to</p> <p>4 cover.</p> <p>5 MR. ARBON: I'll pass the witness.</p> <p>6 MS. HELM: Now I have to do it.</p> <p>7 FURTHER RECROSS EXAMINATION</p> <p>8 BY MS. HELM:</p> <p>9 Q. You would stay in the --</p> <p>10 A. This is a popular document.</p> <p>11 Q. In the IFU and specifically go to the bottom of</p> <p>12 Page 4.</p> <p>13 A. Okay, Page 4, yes.</p> <p>14 Q. Okay. And first of all, do you see on Page 4</p> <p>15 where it says in the middle of the page, it says</p> <p>16 Recovery Cone Removal System and insertion, insertion</p> <p>17 and delivery?</p> <p>18 A. Yes, in the middle, No. 11 is the next number.</p> <p>19 Q. Okay. And then if you go down a little bit</p> <p>20 below -- before that -- below that, towards almost</p> <p>21 the bottom of the page, it says, "Guidewire assisted</p> <p>22 technique"; do you see that?</p> <p>23 A. I see those words.</p> <p>24 Q. And it -- under, below it it says use of a</p> <p>25 guidewire, if it is difficult to align the cone with</p>	<p style="text-align: right;">Page 192</p> <p>1 right. Is that okay if you waive it? I</p> <p>2 recommend it.</p> <p>3 THE WITNESS: I go with your</p> <p>4 recommendation. It would be nice to have a copy</p> <p>5 though.</p> <p>6 VIDEOGRAPHER: This concludes the</p> <p>7 deposition of Dr. Shanon Smith, M.D. on</p> <p>8 April 4th, 2017 at 1822.</p> <p>9 (Concluded at 6:22 p.m.)</p>
<p style="text-align: right;">Page 191</p> <p>1 the G2 filter -- with the G2 filter tip, a guidewire</p> <p>2 may be used to facilitate advancement of the cone</p> <p>3 over the filter tip?</p> <p>4 A. I see those words, guidewire assisted technique</p> <p>5 may be used.</p> <p>6 Q. Okay. Thank you. That's all I have.</p> <p>7 FURTHER REDIRECT EXAMINATION</p> <p>8 BY MR. ARBON:</p> <p>9 Q. That technique didn't work for you, did it?</p> <p>10 A. You know, I actually didn't try that -- oh, you</p> <p>11 mean -- I thought you meant the loop technique. I</p> <p>12 only positioned the guidewire next to the filter and</p> <p>13 the cone following the guidewire, did not engage the</p> <p>14 tip.</p> <p>15 MR. ARBON: I'll pass the witness.</p> <p>16 MS. HELM: No further questions.</p> <p>17 A. So I'm not sure what the guidewire assisted</p> <p>18 means.</p> <p>19 MR. NOVOTNY: Doctor, you have a</p> <p>20 right to review the videotape. You can waive</p> <p>21 that right, is that okay?</p> <p>22 THE WITNESS: Yes.</p> <p>23 MR. NOVOTNY: You have the right</p> <p>24 to review the typed up transcript of your</p> <p>25 testimony, make changes or you can waive that</p>	<p style="text-align: right;">Page 193</p> <p>1 C E R T I F I C A T E</p> <p>2</p> <p>3 I, Christine M. Salerno, RPR, do hereby certify</p> <p>4 that the within and following complete transcript</p> <p>5 contains all the evidence requested to be transcribed</p> <p>6 by me, from the proceedings had in or at the trial of</p> <p>7 the foregoing cause in said court; and that said</p> <p>8 complete transcript is a correct and complete</p> <p>9 transcription of the evidence requested to be</p> <p>10 transcribed from the record made at the time of said</p> <p>11 proceedings or trial.</p> <p>12 Dated this       day of       , 2017.</p> <p>13</p> <p>14</p> <p>15</p> <p>16 _____</p> <p>17 Christine M. Salerno, RPR</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>